UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 13-cv-9244 (RA) OPINION & ORDER

RONNIE ABRAMS, United States District Judge:

This case concerns the diabetes medication ACTOS and whether its manufacturer Takeda violated antitrust laws by misdescribing its patent rights to the Food and Drug Administration (the "FDA"), which in turn delayed the introduction of a generic version of ACTOS. In 2013 and 2015, two groups of purchasers who bought ACTOS directly (the "Direct-Purchaser Plaintiffs," or "DPPs") or through intermediaries (the "End-Payor Plaintiffs," or "EPPs") brought suit against its manufacturer—Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. (together, "Takeda")—alleging violations of federal and state antitrust law. After the case made two trips to the Second Circuit, both parties filed cross-motions for summary judgment. Takeda's motion seeks summary judgment on all of Plaintiffs' claims on the grounds that its alleged anticompetitive conduct—misdescribing its patent rights on ACTOS—is shielded by the so-called "regulatory compliance" defense. *See* Dkt. 709. Plaintiffs' motion seeks partial summary judgment on several issues, including that Takeda is not entitled to the regulatory compliance defense, that Takeda had monopoly power and that Takeda willfully maintained or acquired that power by misdescribing its

patent rights to the FDA. *See* Dkt. 706. The parties also filed *Daubert* motions to exclude various expert witnesses offered by the other side. *See* Dkt. 622, 624, 629, 633, 637, 641 and 644.

For the reasons that follow, Takeda's motion for summary judgment is DENIED, and Plaintiffs' motion for partial summary judgment is GRANTED IN PART and DENIED IN PART. Specifically, Plaintiffs' motion is granted with respect to willful maintenance and denied with respect to monopoly power and the regulatory compliance defense. As for the *Daubert* motions, Plaintiffs' motion to exclude the testimony of Thomas Hoxie, Scott Lassman and Erika Lietzan is GRANTED IN PART and DENIED IN PART, Takeda's motion to exclude the testimony of Guy Donatiello is GRANTED and Takeda's motion to exclude the testimony of Dr. Martha Starr is DENIED. The remaining *Daubert* motions are DENIED as premature with leave to re-file in advance of trial.

BACKGROUND[1]

The Court assumes familiarity with the factual background and underlying regulatory scheme, which have been explained at length in decisions by this Court and the Second Circuit. *See In re ACTOS End-Payor Antitrust Litig. ("ACTOS I")*, No. 13-cv-9244 (RA), 2015 WL 5610752 (S.D.N.Y. Sept. 22, 2015); *In re ACTOS End-Payor Antitrust Litig. ("ACTOS II")*, 417 F. Supp. 3d 352 (S.D.N.Y. 2019); *In re ACTOS Direct Purchaser Antitrust Litig. ("ACTOS III")*, 414 F. Supp. 3d 635 (S.D.N.Y. 2019); *In re ACTOS End-Payor Antitrust Litig. ("ACTOS IV")*, No. 13-cv-9244 (RA), 2020 WL 433710 (S.D.N.Y. Jan. 28, 2020); *In re ACTOS End-Payor Antitrust Litig. ("Takeda I")*, 848 F.3d 89 (2d Cir. 2017); *United Food & Com. Workers Loc. 1776 v. Takeda Pharm. Co. Ltd. ("Takeda II")*, 11 F.4th 118 (2d Cir. 2021). For purposes of this

[1] The following facts are drawn from the parties' statements of undisputed facts and accompanying exhibits and are undisputed unless otherwise stated.

Opinion, the Court restates only the background information necessary to resolve the instant motions.

I. Regulatory Framework

This case centers on the FDA approval process for new and generic drugs, and the interplay between that process and the patent system. When a manufacturer invents a new drug, it inevitably files for patent protection. FDA regulations recognize three distinct "types" of pharmaceutical patents: drug substance patents, drug product patents and method-of-use patents. A "drug substance" patent is one that has claims that protect the active ingredient of the drug, meaning a claim on a specific chemical compound.[2] 21 C.F.R. § 314.53(b).[3] An example would be a patent that includes a claim directed to acetaminophen, the active ingredient in Tylenol. *See Ipsen Biopharms., Inc. v. Becerra*, 108 F.4th 836, 842 (D.C. Cir. 2024). "Drug product" patents, meanwhile, are those that include claims on a "composition" or "formulation" of the drug in product form, 21 C.F.R. § 314.53(b), such as a tablet or capsule that contains the drug substance at a specific dosage, *see Takeda II*, 11 F.4th at 132 n.14 (internal quotation marks omitted). An example of a drug product patent for Tylenol would be one that includes a claim directed to acetaminophen combined with a carrier or shell to form a tablet or capsule, like the familiar Tylenol pills that one can purchase in a drugstore. *See Ipsen Biopharms.*, 108 F.4th at 842 ("[A] *drug* furnishes the pharmacological activity, but a drug *product* is the 'thing' ingested or administered."). "Method-of-use patents," finally, are those that include a claim on a certain method of using the drug, such as a specific method of using Tylenol to treat pain. 21 C.F.R.

[2] Patent claims "are the numbered paragraphs which 'particularly point out and distinctly claim the subject matter which the applicant regards as his invention.'" *Takeda II*, 11 F.4th at 132 (quoting 35 U.S.C. § 112).

[3] Unless otherwise specified, citations to the applicable statute and regulations—21 U.S.C. § 355 and 21 C.F.R. § 314—refer to the versions in effect before 2003, the time period relevant here. Although the regulations were later amended, the parties agree that Takeda's obligations with respect to the Patents were governed by the pre-2003 version.

§ 314.53(b). Manufacturers often file multiple patents on new drugs, with varying degrees of coverage on different drug products and methods of using them. These manufacturers are referred to as "brands," as they develop and release the "brand-name" version of a new drug, akin to Tylenol. *Takeda II*, 11 F.4th at 124–25.

Separate from patent protection, manufacturers must get FDA approval before selling their new drugs. They do so by filing a New Drug Application ("NDA") with the FDA. An NDA must include (among other things) scientific data showing the drug's safety and efficacy, a statement of the drug's composition and proposed labeling. *See Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012). Of significance here, NDAs must also identify any patents on the drug and specify whether those patents are drug substance, drug product or method-of-use patents. *See Takeda I*, 848 F.3d at 98–99. Before 2003—the period relevant here—NDAs did not specify which individual claims were drug substance, drug product or method-of-use; they would instead indicate that the *entire* patent was drug substance, drug product and/or method-of-use if it included at least one claim of that corresponding type. *See* 21 U.S.C. § 314.53(c)(1)(ii). By way of example, a patent that had both method-of-use claims and drug product claims would be identified in the NDA as a method-of-use and drug product patent, without any formal indication as to which claims fell in each category. As later discussed, the rules for identifying patents are set forth in a statutory provision known as the Listing Statute, 21 U.S.C. § 355(b)(1), as well as an implementing regulation called the Listing Regulation, 21 C.F.R. § 314.53 (together, the "Listing Requirement").

Once the FDA approves an NDA, it publishes some of the patent information in a compilation titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." *See Caraco Pharm.*, 566 U.S. at 405–06. As a matter of practice, the FDA does not review the patent information for substantive accuracy and simply publishes that

information as submitted. *See Takeda I*, 848 F.3d at 95 ("The FDA considers its role in publishing the Orange Book to be purely ministerial."). In a notable quirk, however, prior to 2003 the Orange Book did not list out all of the patent types—drug substance, drug product and/or method-of-use—for each listed patent. *See id.* at 99. It instead specified only whether the patent was a method-of-use patent, which meant that other parties could not determine whether it was listed as drug substance or drug product based on the Orange Book entry alone.

Once a new drug is first approved by the FDA, other manufacturers—known as generics—may seek to release a generic version of it. *See id.* at 94. This also requires FDA approval. But because the FDA has already approved the new drug as safe, generics may follow a more streamlined approval process. Instead of having to file a full NDA, generics may instead file an Abbreviated New Drug Application ("ANDA") that "piggy-backs" on the original NDA. *Caraco Pharm.*, 566 U.S. at 404–05. These ANDAs simply show that the generic has the same active ingredients as (and is biologically equivalent to) the brand drug. *See id.* If the FDA agrees, then it generally will approve the ANDA and permit generic entry.

There is, however, an important caveat to ANDA approval: The FDA will not approve an ANDA for a generic drug that would infringe an existing patent. *See id.* at 405. The FDA thus requires generics to declare in their ANDAs that their generic version will not infringe any of patents on the drug listed in the Orange Book. These declarations take several forms, depending on whether any and what type of patents are listed in the Orange Book for the brand-name drug. *See id.* If no patents are listed, or if those listed will expire before the ANDA's approval, the generic simply files a certification to that effect. In Hatch-Waxman parlance, these certifications are known as Paragraph I, II or III certifications, corresponding to the statutory paragraphs that define them. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(III).

Not surprisingly, things become more complicated if live patents are listed in the Orange Book. Generics will have two options, depending on which types of patents are listed in the entry for the brand-name drug. If a listed patent is a drug substance or drug product patent, the generic will need to file a "Paragraph IV certification," which must explain that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). If a listed patent is a method-of-use patent, then the generic may instead file a "Section viii" statement. *Id.* § 355(j)(2)(A)(viii). Because method-of-use patents protect only a method of using a drug, Section viii statements assert that the generic will only market the drug for one or more *other* uses not covered by the method-of use patent. *See Caraco Pharm.*, 566 U.S. at 406.

Although their content may sound similar, filing a Paragraph IV certification as opposed to a Section viii statement has vastly different consequences. Under the Act, filing a Paragraph IV certification is an "artificial" act of infringement, which means the brand can sue the generic for patent infringement upon filing of a certification. *See Takeda II*, 11 F.4th at 125 (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). If the brand chooses to sue, then approval of the ANDA is automatically stayed until thirty months have passed or the patent is found invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). But in order to encourage challenges to invalid patents, the Act provides a bonus for generics who go the Paragraph IV route: The first generic to file a successful ANDA receives a 180-day period during which it has the exclusive right to market a generic version of the drug. *See id.* § 355(j)(5)(B)(iv). Other generics who file their Paragraph IV certifications later are thus subjected to a 180-day "bottleneck" delay. *Takeda I*, 848 F.3d at 89. So while filing a Paragraph IV certification runs the risk of keeping the generic off the market during the lengthy stay, many generics elect to do so anyway in hopes of securing the lucrative

exclusivity window—which can sometimes be worth "several hundred million dollars." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 144 (2013) (internal quotation marks omitted).

The consequences of filing a Section viii statement are far less dramatic. Unlike a Paragraph IV certification, filing a Section viii statement is not an act of infringement, and there is no lengthy period of exclusivity dangled as a reward. *See Takeda II*, 11 F.4th at 125. Even so, successful filers do get a modest benefit: If its Section viii statement is approved, the generic can enter the market even during the 180-day exclusivity period held by the first successful Paragraph IV filer. *See Takeda I*, 848 F.3d at 95. In other words, generics who file Section viii statements avoid the "bottleneck" that will delay the later-filing Paragraph IV applicants.

Whether a generic may file a Section viii statement depends on how the brand described its patents to the FDA. *See Takeda II*, 11 F.4th at 125. As mentioned, Section viii statements are effective only for method-of-use claims—to "carve out" the patented use and avoid infringement. *Id.* (internal quotation marks omitted). So if the brand describes an Orange Book-listed patent as "drug substance" or "drug product," then the generic must file a Paragraph IV certification. *See id.* at 126. If that patent also contains method-of-use claims, then the generic can either file an ANDA with Paragraph IV certifications as to all claims, or they can file a so-called "split certification" containing both a Paragraph IV certification (stating why the drug substance and/or drug product claims are invalid or will not be infringed) and a Section viii statement (carving out the patented use). *See ACTOS II*, 417 F. Supp. 3d at 356.

II. Factual Background

Takeda makes and sells ACTOS, a drug for treating Type-2 Diabetes that features a compound called pioglitazone as its active ingredient. When it first filed the NDA for ACTOS in January 1999, Takeda identified one patent as claiming the drug: U.S. Patent No. 4,687,777 (the

"'777 Patent"). *See Takeda I*, 848 F.3d at 95. This patent, which was set to expire in 2011, had claims directed to pioglitazone or its pharmacologically acceptable salts. Takeda described it as a "drug substance" patent in the NDA, which the FDA approved in 1999. *See id.*

As relevant here, Takeda then obtained two more patents related to ACTOS—U.S. Patent Nos. 5,965,584 (the "'584 Patent") and 6,329,404 (the "'404 Patent," and together "the Patents")—and supplemented its NDA in 1999 and 2002 to identify them as well. Unlike the '777 Patent, these two claimed combinations of pioglitazone along with other drugs, as well as methods of using those combinations. *See* '584 Patent (claiming "[a] pharmaceutical composition comprising an insulin sensitivity enhancer [i.e., pioglitazone] in combination with a biguanide" and a method of treating patients with that composition); '404 Patent (claiming "[a] pharmaceutical composition comprising an insulin sensitivity enhancer [i.e. pioglitazone] in combination with an insulin secretion enhancer" and a method of treating patients with that composition).

As always, Takeda was required to specify in its supplemental NDAs whether these patents were drug substance, drug product or method-of-use patents—which, as discussed above, would control whether generics would need to file Section viii statements or Paragraph IV certifications down the line. At the time, the Listing Requirement required applicants to identify in their NDAs any patents that "claim[ed] the drug for which the applicant submitted the [NDA]" and any patents that "claim[ed] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); *see also* 21 C.F.R. § 314.53(b). Under these provisions, an applicant was permitted to identify a patent as "drug product" only if it "claim[ed]" the drug under submission in the NDA. *See ACTOS II*, 417 F. Supp. 3d at 369.

Neither of the Patents met that standard, as neither "claimed" the drug product ACTOS alone. Instead, both patents included method-of-use claims on methods of using ACTOS in combination with other drugs, and other drug product claims that claimed those combinations. Because those drug product claims recited *combinations* of ACTOS with other drugs, they did not "claim[] the drug" ACTOS within the meaning of the Listing Regulation. *See Takeda II*, 11 F.4th at 127 ("Takeda's '584 and '404 combination patents do not provide any protection over the standalone drug substance pioglitazone or drug product ACTOS.").

For reasons that are sharply disputed, Takeda identified the Patents as "drug product" patents in its supplemental NDAs anyway. *See id.* According to Takeda, it believed at the time that the Listing Requirement set forth an "entire patent," or "identify-all-claim-types," approach. Under this interpretation of the Listing Requirement, once a patent met the requirements for listing, then the NDA filer had to identify *all* of the claim types in the patent—even if those claims did not claim the drug under submission in the NDA. Because the Patents both included method-of-use claims on ACTOS, they had to be listed in the Orange Book, and Takeda was required to identify them in its supplemental NDAs. And pursuant to its "identify-all-claim-types" interpretation, Takeda maintains it was also required to identify the Patents as "drug product," since both had claims on a drug product combination of ACTOS and other drugs.

In line with its ministerial role, the FDA did not conduct its own inquiry as to whether those patent descriptions were correct. Because the Orange Book only displayed whether a listed patent was a method-of-use patent, it identified the Patents publicly as method-of-use patents, without a formal indication that Takeda had also identified them as drug product patents. *See* Dkt. 756 ("Plfs. Rule 56.1 Counterstmt.") ¶¶ 62, 72.

In early 2003, generics began applying to release a generic version of ACTOS once the '777 Patent—the one directly claiming pioglitazone—expired in 2011. *See Takeda II*, 11 F.4th at 128. Because the '584 and '404 Patents would still be valid for several years beyond that, these generics had to file certifications or statements in their ANDAs. On the first day Paragraph IV certifications could be filed, three generics filed split certifications as to the Patents, meaning they filed Paragraph IV certifications certifying that the drug product claims were invalid or would not be infringed by their planned generic versions, as well as Section viii statements carving out the method-of-use claims from the product labels on those generic versions. Plfs. Rule 56.1 Counterstmt. ¶ 74. Several other generics, including Sandoz Inc., later followed suit with split certifications of their own. *See* Dkt. 714 Ex. 5 ("Donatiello Report") ¶ 87; Plfs. Rule 56.1 Counterstmt. ¶ 89.

A handful of generics, however, took a different route. These generics submitted ANDAs with *only* Section viii statements as to the method-of-use claims, without any Paragraph IV certifications as to the drug product claims. *See* Plfs. Rule 56.1 Counterstmt. ¶¶ 85, 89; Donatiello Report ¶ 87. According to Plaintiffs, these generics—including Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (together, "Teva")—chose not to file Paragraph IV certifications because they believed the Patents were not "drug product" patents, as they did not claim ACTOS itself but rather combinations of ACTOS with other drugs. If these ANDAs were approved, these generics would (in theory) have been able to enter the market as soon as the '777 Patent expired, thus bypassing the 180-day bottleneck.

Takeda then sued the generics who had filed Paragraph IV certifications challenging the Patents, and separately filed an infringement suit against Teva. *See* Dkt. 757-1 ("Takeda Rule 56.1 Counterstmt.") ¶¶ 64–76. Soon thereafter, in August 2009, Sandoz submitted a citizen petition

(the "Sandoz Citizen Petition") urging the FDA to deny all ANDAs—including Teva's—that lacked Paragraph IV certifications as to the Patents. *Id.* ¶ 88. According to Sandoz, it had deduced that Takeda had identified the Patents as drug product patents in its supplemental NDAs because Takeda had made assertions that they included "drug product claims" in court filings during its various infringement suits. Dkt. 714 Ex. 47 ("Sandoz Citizen Petition") at 5–6 ("The complaints in these lawsuits confirm that, *in Takeda's own view*, the '584 and '404 patents include both method of use claims and drug product claims.").[4] Since the Patents included drug product claims, Sandoz asserted that all ANDAs were required to include a Paragraph IV certification, and that Teva's should be denied unless it too included one.

Teva responded by filing a comment defending its ANDAs in October 2009. *See* Arnold Decl. Ex. 52 at 7–8. As it explained, there was no evidence that Takeda believed the Patents were "drug product" patents; the Orange Book listed them as only "method-of-use" and Takeda's litigation statements never explicitly confirmed the Patents were drug product. *See id.* at 7 ("It is clear from the complaint that Takeda does not believe that the '584 and '404 patents include drug product claims relevant to ACTOS."). Examining the claims themselves, Teva further asserted that none were "drug product" claims because no claim was directed to ACTOS itself. *See id.* at 7 ("[T]he only drug product claims in those patents are to a drug product containing both pioglitazone and another active ingredient."). Because the Patents were not drug product patents on ACTOS—and because Takeda had not (in Teva's view) identified them as such—Teva urged the FDA to deny the Sandoz Citizen Petition and approve Teva's ANDA with Section viii statements alone.

[4] As used herein, page citations to the parties' exhibits refer to the ECF pagination as opposed to the internal pagination of each document.

These assertions prompted Takeda to act. In internal emails, in-house counsel George Kokkines explained that Takeda was pursuing settlements of its various infringement suits, and that it was "key" to its "settlement strategy" that Teva's original ANDA be denied. *Id.* Ex. 53 at 3; *see also id.* Ex. 55 ("Teva's position [in refusing to provide Paragraph IV certifications] has complicated our efforts to negotiate a potential settlement of these cases."). As a result, Takeda "need[ed] a recommendation on how best to maximize the likelihood of [a denial]." *Id.* Ex. 53 at 3. To that end, Kokkines suggested putting David Fox, a leading regulatory lawyer at Hogan & Hartson LLP, in charge of drafting a response to Teva's comment. *See id.*

Aided by Fox and his team at Hogan, Takeda began crafting its response. In a November 2009 email, another attorney at Hogan emailed Takeda an "outline of potential arguments" that would likely lead to denial of Teva's ANDA. *Id.* Ex. 54 at 2. According to this email, if Takeda submitted a comment to the FDA that "formally" stated that the Patents "contain[ed] claims *other* than method of use claims," the FDA "must defer" to those statements and require Teva to submit Paragraph IV certifications. *Id.* The email cited to a recent FDA decision, the "Prandin Citizen Petition," where the agency had granted a citizen petition like Sandoz's over an objection that the supposed "drug product" claims were combination claims that did not claim the drug under submission. Plfs. Rule 56.1 Counterstmt. ¶¶ 113–18. Under Hogan's interpretation of that decision, all Takeda had to do was state that the Patents were indeed "drug product" patents, and the FDA would automatically accept that characterization and deny ANDAs that lacked Paragraph IV certifications. Arnold Decl. Ex. 54 at 2.

According to Takeda, Fox provided it additional legal advice along these lines. Dkt. 713 ("Takeda Rule 56.1 Stmt.") ¶ 110. He advised it that its original descriptions of the Patents—identifying them as method-of-use and drug product—were indeed correct, even though neither

had a claim on the drug product ACTOS. *Id.* ¶¶ 104–06 ("Mr. Fox advised Takeda that 'if the patent has at least one claim that claims the approved drug product . . . then the whole patent needed to be listed. And then, when looking at the whole of the patent, you have to identify what types of claims are in the patent." (alterations omitted)). Fox further explained that this "identify-all-claim-types" approach was consistent with the decision in the Prandin Citizen Petition, which in his view concluded "that a paragraph IV certification is needed even for drug product or composition claims that do not claim the approved drug product." Arnold Decl. Ex. 49 at 3. As Fox also noted, however, "the law in this area [was] under-developed, with most of it being agency-made in letters and petition responses, but with little in the way of judicial precedent to back up the FDA's claim-by-claim approach to certification described in the Prandin [decision]." *Id.* at 4.

Takeda then sent a private letter to the FDA about these issues on November 23, 2009. Plfs. Rule 56.1 Counterstmt. ¶ 129. In the letter, Takeda confirmed that it had correctly "characterized" both Patents "as containing both drug product and method-of-use claims" in its supplements to the ACTOS NDA. Arnold Decl. Ex. 56 at 8. Because in its view the Patents were correctly listed as drug product patents, Takeda further asserted that any ANDAs (including Teva's) would need to include a Paragraph IV certification. *Id.* at 8 ("Thus, a section viii statement to each patent would be insufficient."). Takeda did not explain the basis for its position, however, and did not mention that it was following the "identify-all-claim-types" theory proposed by Fox. Although that letter was not public, Takeda then filed a copy of it to the public docket of the Sandoz Citizen Petition in January 2010 ("the January 2010 Submission"). *Id.* Ex. 59 at 3. In the cover page, Takeda doubled down on its initial descriptions of the Patents as "drug product," stating that

it had originally "characterized them for [the] FDA . . . as containing both 'drug product' and 'method of use' claims" and "continued to certify" to those descriptions. *Id.*

The FDA granted the Sandoz Citizen Petition on March 15, 2010. Plfs. Rule 56.1 Stmt. ¶ 100. It stated outright that it was granting the petition because Takeda had described the Patents as "drug product," explaining that "[i]n keeping with [its] practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, [the] FDA will rely on Takeda's patent declarations submitted to [the] FDA." Arnold Decl. Ex. 9 at 10. The agency also referred to Takeda's January 2010 Submission, noting that Takeda had "reconfirm[ed]" that the Patents "contain[ed] both 'Drug Product' and 'Method of Use' claims." *Id.*

This outcome meant that Teva's ANDA would not be approved unless it added a Paragraph IV certification. Because Teva would not be considered one of the Paragraph IV first-filers, it would not have been able to enter the market until their 180-day exclusivity period expired—a significant delay. Teva then asked the FDA to reconsider its decision, asserting that the non-method claims in the Patents were not "drug product" claims because they did not claim ACTOS (and instead claimed ACTOS in combination with other drugs). Dkt. 713 ("Takeda Rule 56.1 Stmt.") ¶ 139. This request prompted a patent listing challenge as provided for in 21 C.F.R. § 314.53(f), which permits an ANDA filer to challenge the accuracy of an NDA holder's patent descriptions. The FDA forwarded Teva's submission to Takeda, requesting that it "specifically address and/or confirm that the drug product claims in [the Patents] claim the approved ACTOS drug product." *Id.* ¶ 140.

Up to this point, Takeda had been relying on the "identify-all-claim-types" approach, under which it could identify the Patents as "drug product" even if none of the claims claimed the drug

product ACTOS. Because the FDA was now asking it to confirm that some of the claims *did* indeed claim ACTOS, Takeda could not assert that the Patents were "drug product" under the "identify-all-claim types" approach alone. Some of Takeda's lawyers expressed doubt that it could assert that the Patents claimed the drug product ACTOS, with one Hogan attorney stating that "the claims for which we are trying to draw patent certification indisputably do not apply to the product [ACTOS]." Arnold Decl. Ex. 63 at 16. In other emails around the same time, Fox also expressed skepticism that Takeda could make such a representation. *Id.* Ex. 67 at 2 ("I am not sure I would go as far as saying that this passage shows that [the] FDA was agreeing that if a patent claims a drug substance, but only in conjunction with the use of that substance in an approved drug-drug combo, that the patent meets [the] FDA's Listing Requirement.").

Takeda thus sought the assistance of patent counsel at another firm, Munger Tolles & Olson LLP, in preparing a response to the listing challenge. Takeda Rule 56.1 Stmt. ¶ 147. It specifically asked Munger Tolles for an "opinion as to whether Takeda ha[d] a good faith basis for representing . . . that the 'drug product claims in the '584 and '404 patents claim Takeda's ACTOS drug product and are ones with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug." *Id.* ¶ 151 (quoting Dkt. 714 ("Reed Decl.") Ex. 75 at 2). On May 24, 2010, Munger Tolles provided a draft memo confirming that, in its view, Takeda had a "good faith basis" for representing that the Patents claimed the drug product ACTOS. Reed Decl. Ex. 75 at 8. As the draft memo explained, a patent "claimed" a drug product under the Listing Requirement whenever an unauthorized sale of the drug product would likely induce infringement of the patent. In the case of ACTOS, its labeling stated that it could be prescribed with certain biguanides and insulin secretion enhancers—the *other* drugs claimed in combination with ACTOS in the Patents' drug

product claims. *Id.* at 4. Unauthorized sales of ACTOS, then, could induce infringement of the Patents, since doctors or patients would likely use ACTOS in combination with biguanides or insulin secretion enhancers and thus infringe the drug product claims in the Patents. Were this "induced-infringement" theory correct, Takeda could accurately assert that the Patents "claimed" the drug product ACTOS.

Takeda decided to adopt this advice and submitted a letter response to the FDA on May 28, 2010. *Id.* Ex. 79 ("May 2010 Letter"). The letter re-asserted that the Patents were correctly identified as "drug product" patents under the "identify-all-claim-types" theory of the Listing Requirement. Takeda then staked out its position that it was irrelevant whether the Patents claimed ACTOS, since the "identify-all-claim-types" theory required them to be listed as "drug product" even if they lacked claims on ACTOS itself. *See id.* at 5–6 ("If the applicant believes that some or all of the non-method claims in a validly listed patent may not claim the approved drug product, the applicant would still be expected to make a Paragraph IV certification to the patent."). Takeda then went one step further and, for the first time, stated outright that the Patents did "claim[] the approved ACTOS® drug product." *Id.* at 12. Takeda did not set out the basis for this assertion—the "induced-infringement" theory—in the letter.

In August 2010, Teva contacted Takeda to explore a possible settlement of its ANDA litigation. Plfs. Rule 56.1 Stmt. ¶ 122. Takeda's in-house counsel assumed that Teva had relented because it has "realiz[ed] that a paragraph IV certification w[ould] be required for FDA approval of its pioglitazone ANDA." *Id.* (quoting Arnold Decl. Ex. 74 at 2). At around the same time, Takeda also settled its other ANDA lawsuits on terms that allowed the generics who first filed Paragraph IV certifications to begin selling generic ACTOS by August 17, 2012—a year after the '777 patent expired. Takeda Rule 56.1 Stmt. ¶ 83. It eventually reached a settlement with Teva

in December 2010 that gave it the license to launch generic ACTOS 180 days after the entry date of the first Paragraph IV filers. *Id.* ¶ 91.

As the date of generic entry approached, Takeda anticipated that the price of ACTOS would fall precipitously. Takeda thus implemented a "harvest strategy" in 2011 in order "maximize the profitability of ACTOS," which included "price increases and favorable discount rates." Plfs. Rule 56.1 Stmt. ¶ 128. As Takeda expected, the price of pioglitazone plummeted when the first-filing generics entered the market in August 2012, and dropped further still when the rest were able to launch several months later. Within a few years of generic entry, the average price per pill of pioglitazone had fallen exponentially from its pre-generic peak. Although the parties agree that these price drops occurred, they dispute whether Takeda faced any meaningful competition prior to generic entry, such as from other diabetes drugs.

III. Procedural History

In 2013 and 2015, two putative classes of plaintiffs—the EPPs and DPPs—brought parallel antitrust suits against Takeda alleging among other things that Takeda had monopolized the market for ACTOS. *See* Dkt. 1; Case No. 15-cv-3278 (S.D.N.Y.) Dkt. 1.[5] As relevant here, these claims asserted that Takeda had illegally monopolized that market by misdescribing the Patents as "drug product" patents to the FDA, which delayed the entry of generics like Teva and caused Plaintiffs to pay higher prices for ACTOS. Plaintiffs advanced two theories of causation: first, that Takeda's original descriptions of the Patents as "drug product" in its 1999 and 2002 supplemental NDAs had delayed entry of generics who filed Paragraph IV certifications; and second, that Takeda's

[5] The EPPs and DPPs brought various other antitrust claims, which have since been dismissed. *See, e.g.*, *ACTOS I*, 2015 WL 5610752, at *20 (dismissing EPP claims alleging that Takeda's settlements with generics were unreasonable restraints on trade in violation of state antitrust laws as well as claims alleging overarching conspiracy); *ACTOS III*, 414 F. Supp. 3d at 649 (same for similar DPP claims brought under Sherman Act). Although the two cases have separate dockets, they have since been coordinated onto the EPP docket (No. 13-cv-9244). *See* Dkt. 318 at 1.

later misstatements to the FDA in 2010 specifically delayed Teva's entry, as those misstatements caused the FDA to grant the Sandoz Citizen Petition and force Teva to file Paragraph IV certifications.

After decisions by this Court and the Second Circuit, it was determined that the first causation theory lacked merit. *See Takeda I*, 848 F.3d at 99. As mentioned earlier, even though Takeda allegedly misdescribed the Patents as drug product patents in its 1999 and 2002 supplemental NDAs, the Orange Book identified the Patents only as method-of-use to the public. *See id.* at 98–99 (noting that, before 2003, Orange Book did not disclose whether NDA described each patent as drug substance or drug product). Thus, Takeda's original misstatements could have caused the first-filing generics to file Paragraph IV certifications only if those generics *knew* that Takeda had misdescribed the patents as such. *See id.* at 99. Because the complaint failed to allege such knowledge, the Second Circuit found that this first causal theory failed.

The Circuit concluded, however, that Plaintiffs could proceed under the second causation theory. *See id.* at 100–01. Teva's market entry was delayed not because Takeda had misdescribed the Patents in 1999 and 2002, but because it had done so in *2010*, in response to the Sandoz Citizen Petition. As already discussed, the FDA granted the Sandoz Citizen Petition in reliance on Takeda's alleged misdescriptions, which then forced Teva to file Paragraph IV certifications and be subjected to the 180-day bottleneck delay. As the Second Circuit put it, this theory of causation was "highly plausible," as the FDA "expressly stated that [Paragraph IV certifications] would be required precisely *because* Takeda had described these patents as drug product patents." *Id.* at 100. The Circuit thus directed the Court to address on remand whether Takeda's statements about the Patents were in fact incorrect.

On remand, Plaintiffs amended their complaints to allege that, as with Teva, Takeda's statements in 2010 had delayed entry of other generics. *See* Dkt. 249 at 14. As previewed by the Second Circuit, Takeda then moved to dismiss on the ground that those statements were accurate. It argued that it had correctly described the Patents at all times as "drug product" patents within the meaning of 21 U.S.C. § 355(b)(1), the Listing Statute. *See ACTOS II*, 417 F. Supp. 3d at 362–63. This argument relied on Takeda's "induced-infringement" theory from its May 2010 Letter, which posited that a patent was a "drug product" patent if it included a claim directed to "at least a component of the drug" that could reasonably be asserted in an infringement claim against an unauthorized seller. *Id.* at 362.

The Court rejected this interpretation of the Listing Statute and held that Takeda had misdescribed the Patents as "drug product" in its January 2010 Submission. *See id.* at 358, 369–70. As the Court explained, "an NDA applicant is required to describe a patent as a drug product patent if it claims the NDA drug, that is, it literally reads on the drug." *Id.* at 369. In other words, a patent would be a "drug product" patent on ACTOS if "every element in one of the patent's claims is present in [ACTOS]." *Id.* at 366. Because the combination claims in the Patents recited *additional* elements beyond ACTOS—namely, biguanide and insulin secretion enhancers—they could not be described as "drug product" claims in an NDA for ACTOS, as Takeda had done.

Although the Court rejected Takeda's "induced-infringement" theory of the Listing Statute, it agreed that "there exist[ed] a substantial ground for difference of opinion on this issue," *ACTOS IV*, 2020 WL 433710, at *2, as the statute featured some language supporting Takeda's construction, *see* 21 U.S.C. § 355(b)(1) ("any patent which claims the drug . . . and with respect to which a claim of patent infringement could reasonably be asserted"). The Court thus certified this issue for interlocutory appeal under 28 U.S.C. § 1292(b). *See ACTOS IV*, 2020 WL 433710, at *1.

The Second Circuit affirmed, rejecting the "induced-infringement" theory and holding that the Patents were not "drug product" patents on ACTOS because their claims were "different from the scope of ACTOS." *Takeda II*, 11 F.4th at 132.

These decisions thus narrowed Plaintiffs' claims to a single theory: whether Takeda willfully maintained monopoly power over the ACTOS market by misdescribing the Patents as "drug product" in 2010, which delayed introduction of generic ACTOS and caused Plaintiffs to pay higher prices in the interim. The parties then engaged in discovery and, at the close, filed the cross-motions for summary judgment now before the Court. The parties also filed several *Daubert* motions to exclude the testimony of various experts, which are also before the Court. In addition, in September 2024, the Court granted Plaintiffs' class certification motions and certified end-payor and direct-purchaser classes. *See* Dkt. 794.[6]

LEGAL STANDARDS

Summary judgment must be granted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is material if it 'might affect the outcome of the suit'" and genuinely in dispute if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Roe v. City of Waterbury*, 542 F.3d 31, 35 (2d Cir. 2008) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). In deciding whether a material dispute exists, courts must "resolve all ambiguities and draw all permissible inferences in favor of the party against whom summary judgment is sought." *Donnelly v. Greenburgh Cent. Sch. Dist. No. 7*, 691 F.3d 134, 141 (2d Cir. 2012) (internal quotation marks omitted).

[6] An interlocutory appeal of this class certification is currently pending before the Second Circuit. *See* Case No. 24-2749 (2d Cir.).

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which permits experts to offer opinions when they satisfy several factors:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. In applying this standard, courts take on a "gatekeeping role" and must "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). Trial judges generally should "exclude expert testimony if it is speculative or conjectural or based on assumptions that are so unrealistic and contradictory as to suggest bad faith or to be in essence an apples and oranges comparison." *Zerega Ave. Realty Corp. v. Hornbeck Offshore Transp., LLC*, 571 F.3d 206, 214 (2d Cir. 2006) (internal quotation marks omitted). Experts are likewise not permitted to give opinions as to the meaning and scope of the law, as those issues are reserved for the judge alone. *See United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991). The standard for admissibility of expert testimony at summary judgment is the same as it is at trial, *see Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142–43 (1997), and the party seeking its admission has the burden of establishing admissibility by a preponderance of the evidence, *see Daubert*, 509 U.S. at 592 n.10.

DISCUSSION

I. Motions for Summary Judgment

Before the Court are cross-motions for summary judgment. Plaintiffs' motion seeks partial summary judgment as to three issues: that Takeda had monopoly power over the relevant market,

that it willfully maintained that power by improperly describing the Patents to the FDA and that Takeda is not entitled to the so-called "regulatory compliance" defense. *See* Dkt. 712 ("Plfs. Br.") at 8, 20, 26. Takeda's cross-motion seeks summary judgment that it is entitled to the regulatory compliance defense, which if proven would defeat Plaintiffs' claims in full. *See* Dkt. 710 ("Takeda Br.") at 10.[7]

For the reasons discussed below, the Court finds no genuine dispute that Takeda satisfied the "willful maintenance" element of a monopolization claim by misdescribing the Patents in January and May 2010, which entitles Plaintiffs to partial summary judgment on that issue. The Court also finds, however, that factual disputes remain as to whether Takeda possessed monopoly power in the relevant market, and whether its patent misdescriptions are shielded by the regulatory compliance defense. The motions for summary judgment on those issues are thus denied.

A. Monopoly Power

Plaintiffs move for partial summary judgment on both elements of their monopolization claims. The parties agree that all of the monopolization claims—including the EPP claims brought under state law—are governed by Section 2 of the Sherman Act, 15 U.S.C. § 2. *See ACTOS II*, 417 F. Supp. 3d at 360 n.2. "The offense of monopoly under Section 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Takeda II*, 11 F.4th at 137 (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966) (alterations omitted)).

[7] Takeda's motion also seeks summary judgment on all claims for damages that arise from purchases of generic ACTOS, on the theory that Plaintiffs lack antitrust standing to pursue those claims. *See* Takeda Br. at 28. As Takeda acknowledges, *see* Dkt. 812 at 1 n.1, the Court already rejected this argument in its opinion granting class certification, *see* Dkt. 794 at 21. Takeda's motion for summary judgment on this issue is thus denied.

Plaintiffs first assert that there is no genuine dispute as to whether Takeda had monopoly power—the first element—over the relevant market for ACTOS. "Monopoly power, also referred to as market power, is 'the power to control prices or exclude competition.'" *Tops Markets, Inc. v. Quality Markets, Inc.*, 142 F.3d 90, 97–98 (2d Cir. 1998) (internal citations omitted) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956)). Plaintiffs may prove monopoly power in two ways: directly through evidence that the defendant exercised control over prices or excluded competition, or indirectly by showing that the defendant had a "large percentage share of the relevant market." *Geneva Pharms. Tech. Corp. v. Barr Lab'ys Inc.*, 386 F.3d 485, 500 (2d Cir. 2004). "Courts often rely on indirect proof of market power because direct measures are often difficult or impossible to prove." *Heerwagen v. Clear Channel Commc'ns*, 435 F.3d 219, 227 (2d Cir. 2006). Such indirect evidence functions as a "surrogate" for direct proof of monopoly power, as a defendant's outsized share of a relevant market may signal that it has monopoly power to control prices or exclude competitors within that market. *Id.* (internal quotation marks omitted).

Here, Plaintiffs' motion primarily relies on direct evidence, citing several pieces of evidence as proof of Takeda's monopoly power. Takeda, Plaintiffs say, was able to charge supracompetitive prices for ACTOS, which dropped sharply once generics entered the market in 2012. These prices exhibited a high price-cost ratio, which according to Plaintiffs suggests that Takeda was setting prices far above the competitive level. As further evidence of monopoly power, Plaintiffs also point to data showing that Takeda restricted output of ACTOS before generic entry.

This evidence falls short of warranting summary judgment. At first blush, it may seem that possession of a patent—a legal monopoly—necessarily confers monopoly power. But that is not

so. As courts have often repeated, "[a] patent alone does not demonstrate market power," *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000), or even a "presumption" of it, *C.R. Bard., Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1371 (Fed. Cir. 1998). Even though a patentholder enjoys the right to exclude others from selling products that infringe on the patent, it may well face competition from *other* products, such as "close substitutes for the patented product." *Abbott Lab'ys v. Brennan*, 952 F.2d 1346, 1355 (Fed. Cir. 1991) (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 37 n.7 (1984) (O'Connor, J., concurring)). In other words, a patentholder may not be able to set high prices because non-infringing competitors could undercut it, and may likewise be unable to exclude those competitors as their products do not infringe the patent. "Whether and to what extent a patent confers monopoly power is 'a matter of proof' that must be assessed using the same principles that courts typically apply in antitrust cases." *Regeneron Pharms., Inc. v. Novartis Pharma AG*, 96 F.4th 327, 342 (2d Cir. 2024) (quoting *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965)).

To establish such proof with direct evidence, Plaintiffs must point to "actual detrimental effects on competition," such as evidence that Takeda was restricting output, charging supracompetitive prices or causing decreased quality in the market. *Ohio v. Am. Express Co.*, 585 U.S. 529, 542 (2018) (internal quotation marks omitted). Here, they first point to the fact that Takeda charged high prices for ACTOS, which fell sharply after generics entered the market. As Plaintiffs' expert Dr. Martha Starr explained, Takeda charged comparatively high prices before generic entry and enjoyed a gross margin—a ratio of price to cost—of 87.8% on average. *See* Plfs. Rule 56.1 Stmt. ¶¶ 124, 129–30; *see also* Dkt. 711 ("Starr Report") Ex. 92 ¶ 62 (defining "gross margin" as the "total net sales of the good, minus the cost of goods sold . . . divided by net sales"). Once the first-filing generics entered the market in August 2012, the average price per pill dropped

off sharply, eventually settling at a tiny fraction of its peak value. *See* Plfs. Rule 56.1 Stmt. ¶¶ 129–30; *see also* Starr Report ¶ 57.

While compelling, this evidence does not establish beyond dispute that Takeda was controlling prices in a supracompetitive manner. As many other courts have explained, this pricing pattern happens when virtually every pharmaceutical patent expires—and does not automatically establish monopoly power. "Generics normally enter the market with prices significantly lower than that of the first brand name manufacturers." *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 683 (D.N.J. 2005). This is due to the different business models of brands as opposed to generics. Because brands develop new drugs from scratch, they must heavily invest in upfront costs, including research and development ("R&D") and "substantial marketing and promotional activities." *Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 55 (D.D.C. 2008). The only way to recoup such costs—and stay competitive with other brands—is to charge high prices during the life of the patent. Generics, on the other hand, need not invest much in R&D, as they merely duplicate new drugs developed by brands. *See id.* Nor must they actively promote or advertise their generic versions, because every state has a "substitution law" that permits or requires pharmacies to substitute generic versions for brands when filling prescriptions. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 644–45 (2d Cir. 2015). The bare fact that a brand charged more for a patented drug during its patent term thus "says little" about the brand's "market power," as such pricing patterns may reflect the reality of the brand-name business. *Meijer Inc.*, 572 F. Supp. 2d at 55. This means that a plaintiff must offer "more proof than just a showing that a brand name drug costs more than a generic equivalent." *In re Remeron*, 367 F. Supp. 2d at 683.

Plaintiffs seek to supply that additional proof with Takeda's high price-cost ratios, but those too are insufficient. To be sure, that Takeda was able to enjoy large margins around ninety percent may persuade a jury that it had monopoly power. But the margin figures themselves are inconclusive, because they do not account for R&D and marketing. As Takeda's expert Dr. Anupam Jena explained, Dr. Starr calculated the price-cost margins using the Lerner Index, which measures a product's price minus its marginal cost against its price. *See* Dkt. 759 Ex. 95 ("Jena Report") ¶ 122. Significantly, this metric focuses only on the cost to produce each item, and does not factor in upfront costs like R&D and marketing—the two major expenditures that brands can offset only by setting higher prices for their drugs during their patent terms. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-2503, 2018 WL 563144, at *11 (D. Mass. Jan. 25, 2018). In other words, high margins might signal monopoly power, or they might simply reflect the premium that brands must charge to fund research and marketing against competitors. Because the Lerner Index is blind to these nuances, high scores may not be dispositive as to market power, even when they exceed ninety percent. *See, e.g.*, *In re HIV Antitrust Litig.*, 656 F. Supp. 3d 963, 984 (N.D. Cal. Feb. 17, 2023) ("[A]s other courts have recognized, gross margins are not dispositive on the issue of market power."); *In re Solodyn*, 2018 WL 563144, at *10–12 (denying plaintiffs' motion for summary judgment on monopoly power when brand had "ninety percent" margins). Indeed, the need to offset costly R&D and marketing may well have driven Takeda's pricing strategy here, in light of the evidence offered by Dr. Jena that Takeda's operating margins were in line with those enjoyed by other brands. *See* Jena Report ¶ 126.

The upshot is that, to clear the high bar required for summary judgment, Plaintiffs must offer evidence beyond high margins and post-generic cost drops. The only other evidence they offer is data suggesting Takeda may have restricted output—but that evidence too is disputed. In

her report, Dr. Starr explained how production of ACTOS declined in the months leading up to August 2012, when the first generics entered the market. *See* Starr Report ¶ 70. Although Dr. Starr offered this trend as evidence of output restriction, she also acknowledged that the drop in output coincided with an FDA warning that ACTOS might be linked to bladder cancer. *Id.* Because that would supply an alternative explanation for the downward trend, there is an open factual dispute as to whether Takeda reduced output on its own accord. *See* Jena Report ¶ 128.

To sum up Plaintiffs' direct evidence, the only undisputed facts are that Takeda charged high prices at a high margin before generic entry. Plaintiffs cite no case where summary judgment was granted on monopoly power on those facts. While they make much of the discovery ruling in *In re Aggrenox Antitrust Litigation*, 199 F. Supp. 3d 662, 664–65 (D. Conn. 2016), the more apt decisions are those that denied summary judgment to plaintiffs who offered similarly non-dispositive direct evidence, *see, e.g.*, *In re HIV Antitrust Litig.*, 656 F. Supp. 3d at 985 (denying plaintiffs' motion for summary judgment on monopoly power premised on high pre-generic prices and margins); *In re Solodyn*, 2018 WL 563144, at *10–12 (same when defendant brand had "ninety percent" margins). Indeed, one decision has gone further and expressed skepticism that summary judgment on monopoly power may ever be granted to a plaintiff based on direct evidence alone. *See In re Glumetza*, No. C 19-05822, 2021 WL 1817092, at *7 (N.D. Cal. May 6, 2021) ("Though the Supreme Court approved of direct proof of market power in *Indiana Federation*, there remains a broad gap between affirmance of a direct factual finding of market power versus plaintiffs' request here to take that question from the jury."). In short, while Plaintiffs have a compelling case that Takeda may have had monopoly power, it must save that argument for a jury.

Finally, the fact that the indirect evidence—specifically market definition—is disputed further cuts against awarding summary judgment in Plaintiffs' favor. Plaintiffs assert that the

relevant market consists of ACTOS and its generics, *see* Plfs. Br. at 12–14, while Takeda argues for a broader definition that also includes other antidiabetics that can be substituted for (and that compete with) ACTOS*, see* Dkt. 757 ("Takeda Opp.") at 8–13. Both offer dueling expert reports on this topic, which present a classic "battle of the experts" that cannot be resolved at summary judgment. *F.T.C. v. Quincy Bioscience Holding Co., Inc.*, 646 F. Supp. 3d 518, 528 (S.D.N.Y. 2022). Plaintiffs insist that they may obtain summary judgment anyway, because their *direct* evidence is strong enough to establish monopoly power on its own. *See* Plfs. Br. at 20; Dkt. 766 ("Plfs. Reply") at 5. In their view, it does not matter if Takeda offers contradictory indirect evidence that ACTOS faced competition, since that proof can be ignored entirely.

That argument is flawed. It is true that an antitrust plaintiff may ultimately prevail on direct evidence alone, even if it offers no indirect evidence in its favor. *See In re Aluminum Warehousing Antitrust Litig.*, No. 13-md-2481 (KBF), 2014 WL 4277510, at *35 (S.D.N.Y. Aug. 29, 2014) ("Defining a relevant market is not always required to determine the presence or absence of monopoly power, as monopoly power may be proven directly."); *see also Shak v. JPMorgan Chase & Co.*, 156 F. Supp. 3d 462, 481–82 (S.D.N.Y. 2016) (rejecting argument that market definition is necessary element of monopolization claim). But that does not mean that indirect evidence is entirely irrelevant to summary judgment. Because the relevant market is reasonably in dispute, the Court must assume that *Takeda's* market definition is correct—which means assuming that ACTOS also faced competition in the relevant market from other anti-diabetes drugs. *See Bryant v. Crowe*, 697 F. Supp. 2d 482, 486–87 (S.D.N.Y. 2010) ("On a motion for partial summary judgment, where there are any disputed issues of fact, the court must assume that the nonmovant's version of the disputed issue of fact is correct."). Once that assumption is factored in, it becomes harder still for Plaintiffs to succeed on their argument that Takeda's pricing was supracompetitive,

as it is possible that Takeda set those prices to compete with other anti-diabetes drugs. *See* Takeda Opp. at 9–13 (summarizing evidence suggesting that ACTOS faced competition from "numerous other antidiabetic drugs"). Indeed, another district court reached a similar conclusion, explaining that a defendant's rebuttal evidence of a broader market undermined the plaintiffs' attempt to secure summary judgment using direct evidence alone. *See In re Glumetza*, 2021 WL 1817092, at *7 ("Defendants' evidence of the cross-elasticity of demand between [their brand-name drug] and other [potential substitutes] . . . precludes our reliance on even a rough market definition [in granting summary judgment] here."). Put simply, there is a genuine dispute of material fact as to whether ACTOS faced competition from other antidiabetics, which only further undercuts Plaintiffs' bid for summary judgment on monopoly power.

B. Willful Maintenance

Plaintiffs also move for summary judgment on the second element of their monopolization claims: that Takeda willfully acquired or maintained its monopoly power. *See Takeda II*, 11 F.4th at 137 (citing *Grinnell Corp.*, 384 U.S. at 570–71). To satisfy this element, Plaintiffs must show that Takeda "engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition." *Id.* (quoting *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 108 (2d Cir. 2002)).

Plaintiffs assert that Takeda met this standard by describing the Patents as "drug product" patents in its supplemental NDAs, as well as in its January 2010 Submission and May 2010 Letter to the FDA. Those statements were incorrect, Plaintiffs argue, and had the effect of delaying introduction of generic ACTOS. According to Plaintiffs, had Takeda correctly described the Patents as "method-of-use" patents alone, the generics would have filed only Section viii

statements (and not Paragraph IV certifications) in their ANDAs, which would have allowed them to avoid the 180-day bottleneck delay and release their generic versions much sooner.

Takeda offers several responses. It first argues that Plaintiffs may not seek liability over its *original* descriptions of the Patents in 1999 and 2002, since the Second Circuit already found no causal connection between those statements and the generics' decisions to file Paragraph IV certifications. *See Takeda I*, 848 F.3d at 98–99 (explaining that Orange Book did not reveal Takeda's alleged misstatements, nor did complaint allege that generics were aware of them). It further asserts that it did not make any misstatements in its January 2010 Submission, because it did not explicitly state that the Patents "claimed" ACTOS. Takeda also disputes whether that submission caused the FDA to grant the Sandoz Citizen Petition. And while the May 2010 Letter did explicitly state that the Patents "claimed" ACTOS, Takeda says there is no "evidence that the FDA took any action, or refrained from taking any action, based on [those] statements." Takeda Opp. at 31.

Although the Court agrees that Plaintiffs may not seek liability directly over Takeda's 1999 and 2002 statements, it rejects Takeda's remaining arguments. This Court already held that Takeda's statements in its January and May 2010 submissions were incorrect—the Patents are *not* "drug product" patents—and since the Second Circuit weighed in there no longer remains a serious argument to the contrary. Nor is there any room to argue that the FDA did not rely on those misstatements, as the agency expressly stated it would do just that.

1. 1999 and 2002 Misstatements

At the outset, Takeda is correct that Plaintiffs may not seek liability on the theory that its descriptions of the Patents in 1999 and 2002 delayed entry of generics writ large. This conclusion is nothing new. The Second Circuit already rejected this theory as lacking a causal foundation in

Takeda I, explaining that there were no allegations that the generics were aware of Takeda's original descriptions to begin with. *See* 848 F.3d at 98–99. Because the generics did not know about those statements, there was no basis to say that they caused the generics to file Paragraph IV certifications.

At the same time, however, that does not mean that Takeda's statements in 1999 and 2002 are entirely irrelevant moving forward. To the contrary, those statements still feature in the surviving causation theory: that Takeda's description of the Patents in the January and May 2010 submissions delayed generic entry, because those statements (which reaffirmed that the Patents were "drug product") caused the FDA to grant the Sandoz Citizen Petition. Takeda's statements in 1999 and 2002 form a link in that causal chain. Had Takeda never described the Patents as "drug product" in its 1999 and 2002 submissions, then it would not have stated in its January 2010 Submission that it was "continu[ing] to certify" that the Patents were "drug product" as in its "original declarations." Reed Decl. Ex. 59 at 2 (January 2010 Submission). And by extension, the FDA would not have granted the Sandoz Citizen Petition if Takeda had not made those statements in its January 2010 Submission. *See Takeda I*, 848 F.3d at 96 ("The FDA's ruling was expressly based on the fact that Takeda had described these patents to the FDA as drug product patents.").

Thus, while Takeda is correct that Plaintiffs may not seek liability directly based on Takeda's statements in 1999 and 2002, those statements are also part of the causation theory that remains at issue. Put simply, if Takeda had never described the Patents as "drug product," then the FDA would not have granted the Sandoz Citizen Petition, and generics like Teva would have entered the market earlier than they ultimately did. Accordingly, Plaintiffs must do more than show that the 1999 and 2002 statements were incorrect—they must also show that Takeda's later

statements in 2010 were "improper" and "ha[d] or [were] likely to have the effect of controlling prices or excluding competition." *Takeda II*, 11 F.4th at 137 (internal quotation marks omitted). That is where the Court now turns.

2. January 2010 Submission

Plaintiffs point to two improper statements by Takeda: its statement in its January 2010 Submission that the Patents were "drug product" patents, and its statement in its May 2010 Letter that they "claimed the drug ACTOS." *See* Plfs. Br. at 47–48. If there is no genuine dispute that these statements were (1) incorrect and (2) did or likely led to price control or exclusion of competition, Plaintiffs are entitled to partial summary judgment on the willful maintenance element.

Starting with the January 2010 Submission, there is no doubt that Takeda's statement was incorrect. In that submission, Takeda "confirm[ed]" the listing of the Patents under Takeda's "original patent submissions." Arnold Decl. Ex. 59 at 3. Those original patent submissions—which Takeda attached to the January 2010 Submission—asserted that the "Type of Patent" for both was "[d]rug product" and "method-of-use." *See id.* at 8, 10.[8]

These statements were incorrect, because neither of the Patents is a "drug product" patent under the Listing Requirement. As this Court already held, "a drug product patent" is one that "claims the NDA drug, that is, it literally reads on the drug." *ACTOS II*, 417 F. Supp. 3d at 369. And in order to claim ACTOS, "a drug product claim must be directed to pioglitazone itself—not pioglitazone in combination with other compounds." *Id.* at 366; *see also Takeda II*, 11 F.4th at 131 ("A long line of Supreme Court case law confirms that a combination patent, in general, does

[8] As more fully set forth in Takeda's supplemental NDAs, the original patent submissions read: "US Patent No.: 5,965,584. Expiration Date: June 19, 2016. Type of Patent: Drug product, method of use. Patent Owner: Takeda Chemical Industries, Ltd." and "US Patent No.: 6,329,404. Expiration Date: Jun. 19, 2016. Type of Patent: Drug Product, Method of Use. Patent Owner: Takeda Chemical Industries, Ltd." Reed Decl. Ex. 59 at 8, 10.

not 'claim' its constituent parts."). None of the claims in the Patents meet that standard, as they all claim ACTOS in combination with other drugs. *See* '584 Patent (claiming "[a] pharmaceutical composition comprising an insulin sensitivity enhancer [i.e., pioglitazone] *in combination with a biguanide*" (emphasis added)); '404 Patent (claiming "[a] pharmaceutical composition comprising an insulin sensitivity enhancer [i.e. pioglitazone] *in combination with an insulin secretion enhancer*" (emphasis added)). Put simply, because "the Patents' drug product claims do not literally read on ACTOS, . . . Takeda's 2010 statements to the FDA were inaccurate." *ACTOS II*, 417 F. Supp. 3d at 369–70.

At oral argument, Takeda insisted that the prior decisions in this case did not definitively conclude that its January 2010 Submission was inaccurate. In its view, those decisions rejected only Takeda's "induced-infringement" theory—that the Patents "claim" ACTOS because their combination claims could reasonably be asserted against unauthorized sellers of ACTOS as inducing infringement (as the ACTOS label recommends prescribing ACTOS in combination with the other drugs recited in the combination claims). Takeda thus insists that its *new* theory—that the Patents were correctly described under the "identify-all-claim-types" approach—remains a possibility, since neither this Court nor the Second Circuit has squarely rejected it.

There are more than a few problems with this argument. For one thing, as just explained, the Court already concluded that Takeda's January 2010 Submission was "inaccurate" because "the Patents' drug product claims do not literally read on ACTOS." *Id.* Takeda's contrary argument that its statements were accurate thus runs headlong into the law of the case. *See Doe v. E. Lyme Bd. of Educ.*, 962 F.3d 649, 662 (2d Cir. 2020) ("The law of the case doctrine forecloses reconsideration of issues that were decided—or could have been decided—during prior proceedings." (internal quotation marks omitted)).

Worse, Takeda's new argument would also violate the mandate rule—a "branch" of the law-of-the-case doctrine that "binds the district court" even more "rigidly." *United States v. Aquart*, 92 F.4th 77, 87 (2d Cir. 2024) (internal quotation marks omitted). This strict doctrine bars a district court from considering "not only . . . issues explicitly or implicitly decided on appeal but also . . . issues that were ripe for review at the time of an initial appeal but nonetheless foregone by a party." *Id.* (alterations internal quotation marks omitted). Here, Takeda previously argued in its motion to dismiss that its January 2010 Submission was accurate only because the Listing Requirement followed the "induced-infringement" theory. At no point did Takeda mention its backup "identify-all-claim-types" argument, which would supply an alternate basis as to why its January 2010 Submission was accurate. Even though that argument was "ripe" the first time around, Takeda elected not to pursue it—which means the mandate rule bars it from doing so now. Allowing Takeda to raise this forfeited argument would, in fact, "effectively eviscerate [the mandate rule] by creating an incentive for parties to hold ripe arguments in reserve." *Id.* at 87–88. Put simply, Takeda had its opportunity to argue that the January 2010 Submission was accurate, and the mandate rule strictly prohibits its second bite at the apple.

At any rate, even if the Court were to entertain Takeda's barred-and-forfeited argument, it would reach the same conclusion: It was incorrect to describe the Patents as "drug product" in Takeda's January 2010 Submission. A patent may be described as "drug product" in an NDA only when it claims a formulation or composition of the drug under submission in that NDA, which neither of the Patents do.

This definition of a "drug product" patent flows naturally from the text of the Listing Regulation, which identifies the patents that must be submitted in an NDA and dictates which patent "type" should be used to describe them:

> (b) *Patents for which information must be submitted.* An applicant . . . shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For purposes of this part, such patents consist of drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents. . . .
>
> (c) *Reporting requirements—(1) General requirements.* An applicant . . . shall submit the following information for each patent described in paragraph (b) of this section: (i) Patent number and the date on which the patent will expire. (ii) Type of patent, i.e., drug, drug product, or method of use. (iii) Name of the patent owner. . . .

21 C.F.R. § 314.53(b), (c)(1).

Thus, paragraph (b) identifies the set of patents that must be submitted in an NDA: those that "claim[] the drug or a method of using the drug that is the subject of the new drug application." *Id.* § 314.53(b). The next sentence—the definitional sentence—then divides this set of patents (that claim the drug) into three types: "drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents." *Id.* § 314.53(b). Paragraph (c)(1)(ii) then explicitly requires the applicant to specify the "[t]ype of patent, i.e. drug, drug product, or method of use" in its submission. *Id.* § 314.53(c)(1)(ii). In short, these three sentences control which patents must be submitted and how they are to be described.

According to Takeda, a patent is properly described as "drug product" when it claims a "formulation" or "composition" of *any* drug—even one unrelated to the drug under submission in the NDA. But that would stretch the text beyond its breaking point and disregard all of the surrounding language. When the definitional sentence identifies "drug product" patents as those that claim a "formulation" or "composition" of a drug, it is not referring to any drug whatsoever. It is referring back to the "drug" just identified in the preceding sentence: "the drug that is the

subject of the new drug application." *Id.* § 314.53(b). Indeed, these two sentences appear shoulder to shoulder in the regulatory text, which means they must be read in tandem, not in isolation. *Beecham v. United States*, 511 U.S. 368, 372 (1994) ("The plain meaning that we seek to discern is the plain meaning of the whole statute, not of isolated sentences."). That applies with special force here, as the definitional sentence explicitly refers back to the preceding sentence by referencing "such patents," meaning those just mentioned in the sentence prior that "claim[] the drug . . . that is the subject of the new drug application." *See* 21 C.F.R. § 314.53(b). That leaves little room for ambiguity: When the definitional sentence refers to a "formulation" or "composition" of a drug, it is referencing the same "drug" from the preceding sentence—the one "that is the subject of the new drug application." *See, e.g.*, *Shell Oil. Co. v. Iowa Dep't of Revenue*, 488 U.S. 19, 25 (1988) ("The subsequent reference in the subsection to 'state taxation law' can only be read in light of this antecedent reference to 'adjacent States.'" (alterations and citations omitted)).

The rest of the Listing Requirement points in the same direction. The Listing Statute—which supplies the groundwork for these sentences in the Listing Regulation—puts paramount focus on the drug under submission in the NDA. Much like paragraph (c)(1)(ii) in the Listing Regulation, 21 U.S.C. § 355(b)(1) provides that NDA filers shall identify in their NDA "any patent *which claims the drug for which the applicant submitted the application*, or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted" against an unauthorized seller. 21 U.S.C. § 355(b)(1) (emphasis added). In other words, the singular test for whether a patent must be submitted in an NDA is whether it claims the drug under submission, or a method of using it. By extension, that remains the definitive measure of

whether a patent is a "drug product" patent—namely, whether it is a "formulation" or "composition" of "the drug for which the applicant submitted" the NDA. *Id.*

Takeda's contrary interpretation—that a patent must be identified as "drug product" even if it has no claims on the drug under submission—would also lead to incongruous results. Under its theory, two patents could have the exact same drug product claims, yet only one would need to be identified as a "drug product" patent. For instance, Takeda says that the Patents here had to be so identified because they contained claims on methods of using ACTOS (which qualified them for listing), and because they had drug product claims on some drug (even though it was not ACTOS). *See* 35 U.S.C. § 355(b)(1) (requiring listing of any patent that "claims a method of using" the drug under submission). But assume that another hypothetical patent included the exact same non-ACTOS "drug product" claims as the Patents, without any of the method claims. Under Takeda's theory, this hypothetical patent would not need to be listed in the Orange Book at all—much less be identified as a "drug product" patent—because it contains no claims on ACTOS or a method of using it. In other words, even though two patents could have the exact same non-ACTOS drug product claims, one would be properly identified as a "drug product" patent in an ACTOS NDA, and the other would not. There is no reason for that inconsistency. The far more logical interpretation of the Listing Requirement is that none of these patents is a "drug product" patent in the context of an NDA for ACTOS, since none claim a formulation or composition of it.

In short, the plain meaning of the Listing Statute and Regulation forecloses any argument that a patent may be characterized in an NDA as "drug product" when it has no claims on the drug under submission. The only way to reach Takeda's contrary reading would be to read the definitional phrase "drug product (formulation and composition) patent" in utter isolation. 21 C.F.R. § 314.53(b). But courts do not parse text through a pinhole; they look to nearby provisions

to discern its meaning. Here that surrounding language supplies all the clarity that is needed: Drug product patents are those claim a formulation or composition of the drug under submission in the NDA.

Thus, while Takeda is correct that it was required to identify the Patents in its 1999 and 2002 submissions as "method-of-use" patents, it was not permitted to also describe the Patents as "drug product," because the combination claims in those Patents did not claim ACTOS. There is thus no dispute that, when Takeda re-affirmed in its January 2010 Submission that its "original patent submissions" were correct, it made an inaccurate statement.

Nor is there any dispute that this conduct was anticompetitive, in that it "ha[d] or [was] likely to have the effect of controlling prices or excluding competition." *PepsiCo*, 315 F.3d at 108. Takeda's misstatements in its January 2010 Submission led to a delay in generic entry. As mentioned, the FDA takes a purely "ministerial" role when approving ANDAs and defers without analysis to the NDA holder's description of its patents. Had Takeda admitted that the Patents were not "drug product" patents in its January 2010 Submission to the Sandoz Citizen Petition docket, the FDA would not have granted that petition—and the generics would have been free to release generic ACTOS as soon as the '777 patent expired (rather than being forced to file a Paragraph IV certification and wait out the 180-day bottleneck delay, as Teva was). We can be sure of this fact because the FDA stated it outright when it granted the Sandoz Citizen Petition: "In keeping with our practice of relying solely on the NDA sponsor's patent declaration describing relevant patent claims in Orange Book-listed patents, [the] FDA will rely on Takeda's patent declarations to [the] FDA." Arnold Decl. Ex. 9 at 10. "In other words, the FDA made no attempt to evaluate whether [Takeda's] descriptions were true, but simply accepted them at face value—thus frustrating Teva's Section viii application." *Takeda I*, 848 F.3d at 100 ("The FDA expressly stated that [Paragraph

IV] certifications would be required precisely *because* Takeda had described these patents as drug product patents."). Indeed, even Takeda's own lawyers advised it that the FDA would respond in just the way it did: "It is the characterization of the NDA holder that matters most, and Takeda's original listing of the '584 and '404 patents . . . along with a direct statement to the Sandoz petition docket that the patents contain more than method claims[] should carry the day." Arnold Decl. Ex. 54 at 2 ("[W]here the agency is officially put on notice by the NDA holder that a patent contains non-method claims (as Novo did in the Prandin petition), FDA must defer to the pioneer."). As the Second Circuit put it, "[a] plaintiff could hardly ask for a clearer causal connection." *Takeda I*, 848 F.3d at 100.

At bottom, there is no genuine dispute that Takeda satisfied the "willful maintenance" element of monopolization when it misdescribed the Patents as "drug product" in its January 2010 Submission. In different circumstances, there would be no need to determine whether its later statements in the May 2010 Letter also rose to that level, as its anticompetitive conduct would already be proven based on the January 2010 Submission alone. In this case, however, Takeda has raised the "regulatory compliance" defense, which if successful could shield it from antitrust liability for its misstatements about the Patents, as discussed below. Because it is possible that this defense could apply to its January 2010 Submission but not its May 2010 Letter, the Court thus proceeds to analyze whether its statements in the latter satisfy the "willful maintenance" element as well.

3. May 2010 Letter

As an initial matter, there is no doubt that Takeda also made incorrect statements about the Patents in its May 2010 Letter. After the FDA ruled that Teva would need to submit a Paragraph IV certification as to the Patents, Teva initiated a listing challenge under 21 C.F.R. § 314.53(f).

This process permits any party to "dispute[] the accuracy or relevance of patent information submitted to the agency" by filing a challenge with the FDA. 21 C.F.R. § 314.53(f). However, in line with the FDA's ministerial role, it merely "requests" that the NDA holder "confirm[]" the "correctness" of its submissions. *Id.* If the NDA holder provides that confirmation, the FDA simply denies the listing challenge without performing any analysis of its own. *Id.* ("Unless the application holder withdraws or amends its patent information in response to [the] FDA's request, the agency will not change the patent information in the list.").

Here, after Teva asserted in its challenge that the Patents were not "drug product" patents because they did not "claim" ACTOS, the FDA asked Takeda to confirm whether its patent information was correct—and specifically whether the Patents indeed "claimed" ACTOS. *See* Takeda Rule 56.1 Stmt. ¶ 139. Takeda then retained Munger Tolles, which advised it that there was a "good faith" basis to assert that the Patents "claimed" ACTOS because—under the "induced-infringement" theory—a patent was a "drug product" patent as long as it had a non-method claim that could reasonably be asserted against an unauthorized seller of the drug product. Reed Decl. Ex. 75 at 4–5 ("We believe that there is a good faith argument that sales by a generic under the same circumstances would give rise to a claim for inducement of the composition claims of these patents."). Takeda then adopted that position in its May 2010 Letter responding to the FDA, in which it asserted that "the '584 and '404 patents claim the approved drug or drug product" ACTOS. Arnold Decl. Ex. 16 at 13 ("Takeda also confirms that at least one drug product claim in the '584 patent, and at least one drug product claim in the '404 patent, claims the approved ACTOS® drug product.").

Those statements were incorrect. Both this Court and the Second Circuit have already determined as much in prior opinions, which rejected Takeda's "induced-infringement" theory and

held that a patent "claims" a drug product only if it "read[s] on" that drug product itself. *Takeda II*, 11 F.4th at 132. Because the Patents included only combination claims—that recited ACTOS in combination with other drugs—they "read on" those combinations of drugs, not the "standalone" ACTOS drug product. *Id.* at 131 ("[A] combination patent, in general, does not 'claim' its constituent parts."). Takeda's contrary statements were thus improper.

Much like above, these misstatements also "ha[d] or [were] likely to have the effect of controlling prices or excluding competition." *Takeda II*, 11 F.4th at 137 (internal quotation marks omitted). By regulation, the FDA was required to defer to Takeda's statements when resolving Teva's listing challenge. *See* 21 C.F.R. § 314.53(f). Indeed, "[u]nless [Takeda] withdr[ew] or amend[ed] its patent information in response to [the] FDA's request, the agency w[ould] not change the patent information" identifying the Patents as "drug product." *Id.* So if Takeda had withdrawn or amended its patent information—instead of incorrectly asserting that the Patents were "drug product" and "claimed" ACTOS—Teva's ANDA would have been approved with a Section viii statement alone, and its entry would have been earlier.

* * *

The Court thus finds no genuine dispute that Takeda's misstatements in the January 2010 Submission and May 2010 Letter amounted to the "willful maintenance" element of a monopolization claim. Plaintiffs are thus entitled to partial summary judgment on this issue. That determination, however, could be negated by Takeda's regulatory compliance defense, to which the Court now turns.

C. Regulatory Compliance Defense

Both parties filed cross-motions for summary judgment on Takeda's "regulatory compliance" (or "regulatory mandate") defense. At this stage, it is settled that Takeda

misdescribed the Patents as drug product patents, because neither included a claim on ACTOS alone. Takeda nonetheless argues that this was a reasonable mistake in good faith—in other words, that it genuinely believed that it was required by law to describe the Patents as such, and that its misreading of the law was objectively reasonable.

This sort of defense is known as the "regulatory compliance" defense, and it is unique to antitrust law. In theory, it permits a defendant to avoid antitrust liability if it can show that it "reasonably" and in "good faith" believed that its anticompetitive conduct was required by regulatory law. *ACTOS II*, 417 F. Supp. 3d at 372. Although the Second Circuit has not had occasion to address the viability of this defense, *see Takeda I*, 848 F.3d at 101, other circuits have uniformly recognized its availability to antitrust defendants who acted reasonably and in good faith, *see MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1109–10 (7th Cir. 1983) ("[W]e believe that an antitrust defendant is entitled both to raise and to have the jury consider its good faith adherence to regulatory obligations as a legitimate antitrust defense."); *Phonetele, Inc. v. Am. Tel. & Tel. Co.*, 664 F.2d 716, 737–38 (9th Cir. 1981); *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 740 F.2d 980, 1010 (D.C. Cir. 1984). The First Circuit, in fact, has found this defense applicable to defendants who, like Takeda here, are alleged to have made "an improper submission of [a] patent for listing in the Orange Book." *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 14 (1st Cir. 2020).

As these courts have recognized, the regulatory compliance defense has two prongs: The defendant must have engaged in the challenged conduct under a (1) "reasonable" and (2) "good faith" belief that its actions were required by applicable regulatory law. *See id.* at 13. In other words, even defendants who mistakenly believed that their actions were required can still invoke this defense, provided that their mistake was reasonable *and* they subjectively believed it was

correct. Different courts have looked in various places to assess whether the "reasonableness" prong of the defense is met, including (1) whether the text of the regulatory provisions are ambiguous and can plausibly be read in the way the defendant (mis)construed it, *In re Lantus*, 950 F.3d at 13–14; (2) whether the defendant's misreading is consistent with the "regulatory policy" underlying those provisions, *MCI Commc'ns*, 708 F.2d at 1138; (3) whether others in the industry had adopted the same misinterpretation, as evidenced by "custom and practice," *In re Lantus*, 950, F.3d at 13; and (4) whether "any legal opinions" supported the defendant's misinterpretation, *id.* Adjudicating the "good-faith" prong, meanwhile, requires examining whether a defendant acted out of a subjective belief that its conduct was required by regulatory law, as opposed to for "competitive" reasons. *See S. Pac. Commc'ns*, 740 F.2d at 1009.

Takeda asserts that its misstatements about the Patents—that they were drug product patents and claimed ACTOS—meet both prongs of this standard. Plaintiffs disagree. They argue that Takeda's misstatements were based on objectively unreasonable interpretations of the Listing Requirement—the "identify-all-claim-types" and "induced-infringement" theories— that were not supported by its plain language or industry practice. Plaintiffs contend that Takeda did not make those misstatements in good faith either, as it made them with the aim of delaying generic entry as opposed to out of a genuine effort to comply with the Listing Requirement.

Before diving into those issues, however, the Court must address a threshold question: whether the reasonableness and good-faith prongs should be adjudicated by a judge or a jury. Starting with the easier of the two, all parties agree that subjective good faith is a question of fact for a jury. The Court shares that view as well. Subjective good faith is a "question of fact" that "inherently requir[es] resolution by a jury." *Harlow v. Fitzgerald*, 457 U.S. 800, 816 (1982). The Court may thus resolve this question at summary judgment only if there is no genuine dispute that

Takeda "subjectively 'in good faith concluded' that its actions were required by regulation." *In re ACTOS Antitrust Litig.*, 628 F. Supp. 3d 524, 534 (S.D.N.Y. 2022) (citations omitted).

The more nuanced issue is the reasonableness prong. The parties largely disagree over whether a judge or jury should resolve it. In a supplemental letter requested by the Court, Takeda took the position that, unless the Court finds that there is no dispute of material fact, objective reasonableness must be determined by a jury in its entirety. *See* Dkt. 821 at 1. To be sure, Takeda acknowledges that juries may not determine whether Takeda's interpretation of regulatory law was correct, as that is a pure question of law that only a court may resolve. *See id.* at 1–2. It nonetheless asserts that whether its interpretation was objectively *reasonable* is a different inquiry—one involving a mixed question of law and fact—that must be put to a jury. *Id.* at 2. It analogizes the reasonableness prong of the regulatory compliance defense to objective reasonableness in Sarbanes-Oxley retaliation claims and the "sham exception" to *Noerr-Pennington* immunity, two issues that also involve reasonableness and are jury questions. *Id.* at 3.

For the most part, Plaintiffs see the issue differently. On one hand, Plaintiffs agree with Takeda that a jury should resolve disputed facts relevant to the reasonableness prong, including industry practice. *See* Dkt. 822 at 1. On the other, Plaintiffs assert that a court, not a jury, must resolve the ultimate question of whether a defendant's mistake of regulatory law was objectively reasonable. This conclusion, Plaintiffs argue, is consistent with the Supreme Court's decision in *Merck Sharp & Dohme v. Albrecht*, which held that certain preemption issues involving regulatory agencies must be decided by the court. 587 U.S. 299, 316 (2019). The Court there explained that juries are ill equipped to answer issues that involve construction of "written instruments" and interpretation of "agency decisions in light of the governing statutory and regulatory context." *Id.* (internal quotation marks omitted). In short, while juries may be well suited to answer questions

involving "simple historical fact," judges are "better positioned" to resolve others that veer into statutory interpretation and regulatory law. *Id.* at 317–18 (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996)).

The Court largely agrees with Plaintiffs. While a jury may play a limited role in deciding subsidiary questions about "simple historical fact," objective reasonableness is ultimately a question of law that must be decided by a court. *Id.* (quoting *Markman*, 517 U.S. at 388). As the Supreme Court explained in *Albrecht*, juries are poorly suited to confront issues that involve interpreting written instruments and agency decisions, both of which are implicated here. In deciding whether Takeda's misinterpretation of the Listing Requirement was objectively reasonable, the decisionmaker will need to determine among other things whether Takeda's conduct was supported or contradicted by the plain language of the Listing Statute and Regulation. *See, e.g.*, *Organon, Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 460 (D.N.J. 2003) (resolving reasonableness prong by examining whether Listing Regulation was capable of "two equally plausible interpretations"); *In re Lantus*, 950 F.3d at 14 (same by assessing whether Listing Statute was "unambiguous"). Construing a statute's plain language and assessing ambiguity are not issues that may be left to a jury. *See Markman*, 517 U.S. at 386 ("[C]onstruction of written instruments is the province of the court alone."). Nor are juries equipped to discern the meaning of "agency decision[s]" like the Prandin Citizen Petition, *Albrecht*, 587 U.S. at 316, which a jury would also need to confront when taking up Takeda's reasonableness arguments, *see* Takeda Opp. at 29 (arguing that Prandin Citizen Petition indicated Takeda's misinterpretation was correct at the time).

Takeda urges the Court to follow the approach from Sarbanes-Oxley retaliation claims, in which a jury decides whether a whistleblower had a reasonable belief that his employer violated

the law. Yet there is a key difference between that issue and the regulatory compliance defense: Sarbanes-Oxley claims do not require a jury to parse statutory text or interpret legal decisions. "An employee does not need to specifically allege fraud," or even "reference a specific statute in order to engage in protected activity [under the Sarbanes-Oxley Act]." *Barker v. UBS AG*, 888 F. Supp. 2d 291, 296–97 (D. Conn. 2012) (citing *Van Asdale v. Int'l Game Tech.*, 577 F.3d 989, 997 (9th Cir. 2009)). Takeda's analogy to Sarbanes-Oxley is thus unpersuasive, as adjudicating the reasonableness prong requires the sort of legal training that is well outside the ken of a lay jury. The same is true of Takeda's appeal to the "objectively baseless standard" in the *Noerr-Pennington* doctrine, which does not call for the type of textual and regulatory analysis at play in the objective reasonableness inquiry here. *See Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62–63 (1993) (explaining that suit is "objectively baseless" when "defendant lacked probable cause to institute an unsuccessful civil lawsuit").[9]

A more apt analogy is qualified immunity. Much like the reasonableness prong of regulatory compliance, qualified immunity is an affirmative defense that turns in part on whether an actor made a reasonable mistake of governing law. *See Zellner v. Summerlin*, 494 F.3d 344, 367 (2d Cir. 2007).[10] Courts resolve that inquiry by deciding whether the actor violated "clearly established" law, as evidenced by "decisional law of the Supreme Court and the applicable circuit court." *Soukaneh v. Andrzejewski*, 112 F.4th 107, 122 (2d Cir. 2024) (internal quotational marks

[9] The Court also rejects the parties' dueling arguments that the Seventh Circuit resolved this issue in their respective favors in *MCI Communications*. While that decision correctly held that a jury may not construe the meaning of an agency decision, it did not clearly decide whether a judge or jury must be the ultimate arbiter of the reasonableness prong. *See MCI Commc'ns*, 708 F.2d at 1135 ("[T]hat approach improperly allowed the jury to decide what amounted to a question of law.").

[10] Although qualified immunity is a useful analogy for dividing labor between judges and juries, the Court does not mean to suggest that qualified immunity and regulatory compliance use a similar standard for what qualifies as "reasonable." *See, e.g.*, *Provost v. City of Newburgh*, 262 F.3d 146, 160 (2d Cir. 2001) (characterizing qualified immunity as a notably "forgiving standard" to satisfy).

omitted). "Juries are hardly suited" to answer such questions, which "require analysis of legal concepts" that will inevitably be outside their competencies. *Stephenson v. Doe*, 332 F.3d 68, 81 (2d Cir. 2003) (internal quotation marks omitted). By the same logic, juries are not qualified to answer the ultimate question of whether an antitrust defendant made a reasonable mistake of law in attempting to comply with the applicable regulations.

That does not mean, however, that juries have no factfinding role whatsoever. As with qualified immunity, there may be factual questions underlying the reasonableness prong that juries are well suited to answer. *See Zellner*, 494 F.3d at 368 ("Once the jury has resolved any disputed facts that are material to the qualified immunity issue, the ultimate determination of whether the officer's conduct was objectively reasonable is to be made by the court."). For instance, one fact material to objective reasonableness is industry practice—whether others in the industry shared defendant's misinterpretation of regulatory law, as evidenced by their past conduct. *See In re Lantus*, 950 F.3d at 13 (referring to "custom and practice in the industry"). And unlike issues of statutory interpretation and ambiguity, the question of what constituted "standard industry practice[]" is a "matter of historical fact" that a jury is well equipped to determine. *Chem. Leaman Tank Lines, Inc. v. Aetna Cas. & Sur. Co.*, 89 F.3d 976, 987 (3d Cir. 1996). Juries regularly make factual assessments of this sort, in all manner of contexts. *See, e.g.*, *SR Int'l Bus. Ins. Co., Ltd. v. World Trade Ctr. Props., LLC*, 467 F.3d 107, 135–36 (2d Cir. 2006) (jury determining industry custom as part of contract dispute); *Bilzerian*, 926 F.2d at 1295 (jury hearing testimony about industry practice in order to "evaluate a defendant's conduct against the standards of accepted practice"); *Jackson v. Domtar Indus, Inc.* 35 F.3d 89, 93 (2d Cir. 1994) ("Although [the defendant's] arguments regarding industry practice and the standard of reasonable care may be persuasive, they are properly arguments for the jury."); *303 W. 42nd St. Enters., Inc. v. I.R.S.*, No.

93-cv-4483 (LBS), 2000 WL 666339, at *4 (S.D.N.Y. May 22, 2000) (Sand, J.) ("With respect to industry practice, the verdict form also asked the jury to determine, preliminarily, whether [the defendant] had established by a preponderance of the evidence that a significant segment of the industry in which it was engaged [committed a similar mistake in tax filings]."). Simply put, juries often hear "testimony concerning the ordinary practices" of various industries in order "to evaluate the conduct of the parties against the standards of ordinary practice in th[ose] industr[ies]." *Marx & Co., Inc. v. Diners' Club Inc.*, 550 F.2d 505, 509 (2d Cir. 1977); *see also Joffe v. King & Spalding, LLP*, No. 17-cv-3392 (VEC), 2019 WL 4673554, at *17 (S.D.N.Y. Sept. 24, 2019) (addressing use of such testimony to explain "applicable standard of care" to jury in legal malpractice cases).

Given the relative competencies of judges and juries, the Court thus concludes that objective reasonableness is a legal question that a court must ultimately determine. Juries may be enlisted to adjudicate subsidiary factual disputes, such as industry custom and other matters of "historical fact." *Markman*, 517 U.S. at 388 (internal quotation marks omitted). As always, if there is no genuine dispute over any material fact, then the Court may adjudicate objective reasonableness as a matter of law at summary judgment.

The Court thus turns to both the reasonableness and good-faith prongs of the regulatory compliance defense to assess whether there is any genuine dispute of material fact as to either. Because Takeda made two separate misstatements—the January 2010 Submission and the May 2010 Letter—that amount to willful maintenance, the Court analyzes each statement separately. As elaborated below, it finds that there are factual disputes as to the reasonableness and good-faith prongs that preclude summary judgment as to the January 2010 Submission, and that there are

factual disputes as to the good-faith prong that preclude summary judgment as to the May 2010 Letter.

1. January 2010 Submission

Takeda argues that the regulatory compliance defense shields it from antitrust liability over its January 2010 Submission to the FDA, which asserted that the Patents were "drug product" patents with respect to ACTOS. Although those statements were wrong, Takeda argues that they were based on a reasonable and good-faith misinterpretation of the Listing Requirement, as manifested in Takeda's "identify-all-claim-types" theory. According to Takeda, it reasonably believed at the time that once a patent qualified for submission in an NDA, the applicant was required to identify each claim type present in the patent—drug substance, drug product or method-of-use—even for claims that did not claim the drug under submission in the NDA.

a. Objective Reasonableness

Takeda must first show that the "identify-all-claim-types" theory was a reasonable misinterpretation of the Listing Requirement. No court, unfortunately, appears to have set forth a concrete framework for deciding what conduct qualifies as objectively reasonable for purposes of the regulatory compliance defense. *See, e.g.*, *In re Lantus*, 950 F.3d at 13–14 (discussing reasonableness prong without reference to particular framework or specific factors); *Phonetele*, 664 F.2d at 737–78 (same). Even so, a review of the relevant decisions reveals several factors that are relevant to the reasonableness inquiry: (1) whether the text of the regulatory rules are ambiguous and can plausibly be read in the way the defendant misconstrued it, *see In re Lantus*, 950 F.3d at 13–14; *Organon*, 293 F. Supp. 2d at 460; (2) whether the defendant's misreading is consistent with the "regulatory policy" underlying those rules, *MCI Commc'ns*, 708 F.2d at 1138; (3) whether others in the industry have adopted the same misinterpretation, as evidenced by their

"custom and practice," *In re Lantus*, 950 F.3d at 13; and (4) whether the defendant received "any legal opinions" supporting its misinterpretation, *id.* As previewed above, the first two factors—text and regulatory policy—are legal issues for the Court, while the latter two are factual issues suitable for jury determination.

Starting with the first factor, Takeda faces a challenge: The "identify-all-claim-types" theory is not only wrong, but at odds with the plain text of the Listing Statute and Regulation. As already explained, the only possible definition of a "drug product" patent is one that includes a claim on a "formulation" or "composition" of the drug under submission in the NDA. 21 C.F.R. § 314.53(b). Takeda's contrary interpretation—that a "drug product" patent is one that claims *any* drug product, even one unrelated to the NDA—requires plucking select clauses of the Listing Regulation and ignoring the surrounding text. Such a construction conflicts with settled rules of statutory interpretation. *See Beecham*, 511 U.S. at 372 ("The plain meaning that we seek to discern is the plain meaning of the whole statute, not of isolated sentences."). In short, Takeda's misinterpretation runs up against the plain text of the Listing Regulation—a red flag that its misinterpretation may not have been reasonable.

This friction with the plain language of the Listing Requirement separates this case from others where defendants prevailed on the regulatory compliance defense before trial. In *Organon, Inc. v. Mylan Pharmaceuticals, Inc.*—which Takeda cites favorably—the district court found that the defendant was entitled to the defense because another part of the Listing Statute was ambiguous. *See* 293 F. Supp. 2d at 453. The defendant there identified a patent in its NDA as a "method-of-use" patent, even though the claimed use was an "off-label" use that had not been approved by the FDA. *Id.* at 459. Another company then filed antitrust claims asserting that this listing was incorrect, because the Listing Requirement supposedly did not permit a patent to be

identified as "method-of-use" if it claimed an off-label use. As the district court noted, however, the Listing Regulation required the submission of any method-of-use patent "that claim[ed] indications or *other conditions of use* of a pending or approved application." *Id.* at 460 (quoting 21 C.F.R. § 314.53(b)). This language—particularly the "other conditions of use" phrase—was susceptible to two "equally plausible interpretations," including the defendant's construction under which listing was required for off-label method-of-use patents. Given that ambiguity, the court concluded that the defendant had a "reasonable basis" for describing its patent as "method-of-use" and dismissed the antitrust claims against it. *Id.* at 460.

The same can hardly be said here. While Takeda is correct that the Listing Statute and Regulation do not state outright that drug product patents must have a claim on the drug under submission, the plain language makes that relatively clear—drug product patents must claim a "formulation" or "composition" of the "drug that is the subject of the new drug application." 21 C.F.R. § 314.53(b). Takeda's contrary interpretation is at best an unnatural reading of the Listing Requirement.

Takeda also argues that the "identify-all-claim-types" theory finds support in regulatory policy—the second factor—but the Court is unconvinced. *See* Dkt. 769 ("Takeda Reply") at 6. Here Takeda points to an FDA decision, the "Prandin Decision," which it says sets forth a policy that NDA filers were to identify their patents based on all of the claim types that appeared in them, even if those claims did not read on the drug under submission. *See* Arnold Decl. Ex. 10 ("Prandin Decision"). In that matter, Novo Nordisk submitted a drug called Prandin for FDA approval and described one of its patents as a "drug substance, drug product, and a method-of-use patent" in its NDA. Prandin Decision at 19. After a citizen petition was filed, another party filed a submission challenging Novo Nordisk's descriptions and, like Teva here, argued that the patent was not a

"drug product" patent because the supposed "drug product" claims were combination claims of Prandin with other drugs. *See* Reed Decl. Ex. 51 at 2. The FDA rejected that argument and required all ANDA filers to include both Paragraph IV and Section viii statements, again like Teva here. *See* Prandin Decision at 19.

This decision would help Takeda's position if the FDA had (1) independently analyzed the Prandin patent claims and determined that they did *not* claim Prandin, and (2) required ANDA filers to include Paragraph IV certifications anyway. But nothing indicates the FDA did that. To the contrary, it appears that—consistent with its ministerial role—the FDA simply deferred to Novo Nordisk's description of the patents as "drug product" without analysis, and required ANDA filers to submit Paragraph IV certifications simply because Novo Nordisk had asserted they were drug product patents. *See id.* ("We agree that the '358 patent is listed as a drug substance, a drug product, and a method-of-use patent, and are granting your request."). In fact, Takeda's own outside counsel at Hogan interpreted the Prandin Decision as doing exactly that, explaining how it demonstrated that the "FDA must defer" to the NDA holder's description of the patents and would not perform an independent analysis of its own. Arnold Decl. Ex. 54 at 2 ("[W]here the agency is officially put on notice by the NDA holder that a patent contains non-method claims (as Novo did in the Prandin petition), [the] FDA must defer to the pioneer.").

The Prandin Decision is thus no different from what happened to Teva here: A challenger asserted that no Paragraph IV certifications were needed because the patent was not actually a "drug product" patent, but the FDA required those certifications—without analyzing the claims itself—because the NDA filer had identified the patent as "drug product." Put simply, the Prandin Decision never explored whether Novo Nordisk correctly described its combination patents as "drug product," which undercuts Takeda's attempt to show the same for itself.

In sum, neither the plain language nor regulatory policy establish that Takeda's mistake of law was an objectively reasonable one. On the other hand, the Court is not persuaded that these factors prove that Takeda's mistake was unreasonable either. While Takeda's misinterpretation of the Listing Requirement runs up against its plain language, Takeda is correct that its misreading was not entirely foreclosed by it—which leaves the door open to an ultimate finding that its mistake was reasonable. The Court must therefore turn to the other factors, industry practice and legal opinions, to assess if there is a genuine dispute as to whether Takeda's mistake was objectively reasonable. Because these factors are subsidiary factual inquiries that should be resolved by a jury, the Court's role is to assess whether there is any genuine dispute over industry practice and any relevant legal opinions.

Starting with industry practice, Takeda points to several pieces of evidence as proof that others in the industry shared its mistaken view that an NDA filer was required to identify all claim types in every patent that qualified for the Orange Book. First, Takeda argues that the Prandin Decision shows that at least one other actor in the industry, Novo Nordisk, also followed the "identify-all-claim-types" approach when it described its combination patent as "drug product." Second, it points out that, unlike Teva, more than half of the generics that filed ANDAs submitted Paragraph IV certifications, which indicates they shared Takeda's view that such certifications were required even for patents that did not claim the drug under submission. Third, Takeda offers expert opinions from several regulatory lawyers that Takeda's description of the Patents as "drug product" was supported by industry practice.

This evidence is far from conclusive, and certainly short of that needed for summary judgment. Although Novo Nordisk's patent descriptions are consistent with the "identify-all-claim-types" theory—since they characterized a patent with combination claims as a "drug

product" patent—the conduct of a single actor can hardly be deemed an industry practice. If anything, the fact that Takeda can cite only one other instance of similar conduct by a brand suggests there was no "industry practice" to speak of. And at any rate, it is not clear why Novo Nordisk chose to describe its patents as "drug product," a highly relevant fact. It could be that Novo Nordisk was simply describing its patents as "drug product" in bad faith, in a bid to force generics to file Paragraph IV certifications. If that were true, then its behavior would be evidence of only anticompetitive misconduct, not an "industry practice" of others making the same mistake as Takeda.

Novo Nordisk's behavior would be far more significant if Takeda could cite others who acted in step with it. The best Takeda has to offer is that most of the ANDA filers in its case submitted Paragraph IV certifications. *See* Donatiello Report ¶ 87; Plfs. Rule 56.1 Stmt. ¶¶ 47–76. This behavior could suggest that these generics believed Takeda's "drug product" descriptions were correct, as it may be that they reviewed Takeda's patents and independently concluded they were "drug product" patents that required Paragraph IV certifications (as the Orange Book did not reveal what descriptions Takeda had used).

While promising, there are multiple unknowns that undercut the strength of this evidence. For one thing, five of the Paragraph IV filers submitted their ANDAs after the FDA ruled in the Sandoz Citizen Petition that Paragraph IV certifications would be required, which makes it impossible to discern whether these generics subscribed to Takeda's "identify-all-claim-types" theory. *See* Plfs. Rule 56.1 Stmt. ¶¶ 72–76 (noting that these generics filed ANDAs after the FDA's March 2010 ruling on the Sandoz Citizen Petition). That leaves six generics who initially filed ANDAs with Paragraph IV certifications and five who initially filed only Section viii statements—meaning that about half at most shared Takeda's view. *See* Donatiello Report ¶ 87.

And even among that half, there are alternate explanations for their behavior that remain plausible on this record. As the Second Circuit explained, there are "significant incentive[s]" to filing a Paragraph IV certification, as successful first-filers will receive a lucrative 180-day exclusivity period. *Takeda II*, 11 F.4th at 136. The Paragraph IV filers may thus not have shared Takeda's misunderstanding about the "identify-all-claim-types" theory yet filed Paragraph IV certifications anyway. And even apart from the exclusivity period, the Paragraph IV filers may have deduced that Takeda had identified the Patents as "drug product" based on statements Takeda made in its infringement suits, as Sandoz claimed it did in its citizen petition to the FDA. *See* Sandoz Citizen Petition at 5–6 ("The complaints in these lawsuits confirm that, *in Takeda's own view*, the '584 and '404 patents include both method of use claims and drug product claims."). This would also undermine Takeda's claim of an industry practice, as it is possible that the Paragraph IV filers did so because they believed Takeda had characterized the Patent as "drug product," as opposed to out of a belief that the "identify-all-claim-types" theory was correct.

Takeda also cites the opinions of three experts—Thomas Hoxie, Scott Lassman and Erika Lietzan— as evidence that Takeda's patent descriptions were "consistent" with industry practice at the time. Arnold Decl. Ex. 85 ("Lietzan Reply Report") ¶ 21. But these opinions appear to rely on the exact same evidence of "industry practice" just discussed above, which is not particularly persuasive. Lassman, for instance, opined that "most of the regulated industry" believed at the time that ANDAs had to file Paragraph IV certifications even on "claims that do not cover an approved aspect of the drug," consistent with the "identify-all-claim-types" theory. Arnold Decl. Ex. 80 ("Lassman Report") ¶¶ 62–64. Yet the only evidence Lassman cites for this "widespread industry behavior" is the fact that many of the ANDA filers in the ACTOS case filed Paragraph IV certifications—which as already noted is far from conclusive evidence of industry practice. *Id.*

¶ 64. The same is true of Lietzan, who opined that "Takeda's description of patent type was consistent with practice at the time." Lietzan Reply Report ¶ 21. The only evidence offered in support of that conclusion, however, is the fact that Novo Nordisk described its patent like Takeda did in the Prandin matter. *See id.* As for Hoxie, his report does not specifically refer to industry practice by name, though it does mention the Prandin Decision and the fact that many ANDAs filed Paragraph IV certifications as to the Patents. *See* Arnold Decl. Ex. 82 ("Hoxie Report") ¶ 31.[11] Once again, that evidence does not conclusively establish that Takeda's misinterpretation was consistent with industry practice, so Hoxie's opinion does little to establish that fact.

Takeda also asserts that the legal opinions it obtained from outside counsel show that its misinterpretation was reasonable. As it points out, it received an opinion from its "outside expert regulatory lawyer, David Fox at Hogan," stating that Takeda was required to identify all claim types in the patents, including the drug product claims that did not claim ACTOS. Takeda Br. at 14 (citing Takeda Rule 56.1 Stmt. ¶ 158); *see also* Plfs. Rule 56.1 Counterstmt. ¶¶ 104–05.

As an initial matter, Plaintiffs dispute whether such legal opinions are relevant to the reasonableness prong at all. In their view, whether a defendant sought and followed an outside legal opinion bears only on its subjective good faith—whether it chose the regulatory course it did because it believed that conduct was required by regulatory law. While this evidence's link to the subjective prong is clear, Plaintiffs assert that such legal opinions are not relevant to the reasonableness inquiry at all. And while the First Circuit noted that "legal opinions" were relevant to the "reasonableness prong," that statement was not a holding and was not supported by much analysis. *In re Lantus*, 950 F.3d at 13 (explaining only that summary judgment was premature

[11] At argument, Takeda suggested that Hoxie had also offered the opinion that his former employer, Novartis, had shared Takeda's view of the "identify-all-claim-types" approach. *See* Dkt. 816 ("MSJ Tr.") at 89–90. His report does not specifically set forth that opinion, however, nor does it identify any actual examples of Novartis describing a patent like Takeda did here. It would thus be entitled to only limited weight.

because "the record d[id] not yet contain any evidence about . . . what if any legal opinions [defendant] sought and obtained before submitting the patent").

To some extent, Plaintiffs have a point. That an antitrust defendant received and followed legal advice supporting its course of action is highly relevant to subjective good faith, and that is the natural home for such evidence in the regulatory compliance framework. At the same time, however, the presence of contemporaneous legal opinions could bear on objective reasonableness as well. Just like the behavior of other actors in an industry, the advice that lawyers were giving clients could reflect the common or prevailing understanding of an industry at the time of a defendant's mistake, which could suggest that such a mistake was reasonable.

In any event, even assuming that the legal advice Takeda received is a factor in objective reasonableness, that advice would not entitle it to summary judgment. As already discussed, both the plain language and regulatory policy weigh against the reasonableness of Takeda's mistake, and industry practice is neutral at best—which means Takeda would need to make a considerable showing of "legal advice" were it to secure summary judgment. In fighting that uphill battle, the only legal advice Takeda points to is the guidance from Fox and Hogan advising it to describe the Patents as "drug product" under the "identify-all-claim-types" theory. *See* Reed Decl. Ex. 91 ("Fox Decl.") ¶ 7. That advice, however, is just one data point, which does not by itself establish the objective reasonableness of Takeda's misinterpretation (although it could certainly have more force in showing Takeda's good faith under the second prong). And more problematically, evidence in the record suggests that Fox's opinion may have been outcome-driven as opposed to independent and impartial. In internal emails, Takeda's in-house counsel George Kokkines stated openly that they were seeking Fox's input in order to get "a recommendation on how to best maximize the likelihood" that "Teva be deemed a later filer"—meaning by forcing it to file a

Paragraph IV certification. Arnold Decl. Ex. 53 at 3. Fox also made statements suggesting that his legal opinions were not the prevailing view, including his comments that the "law in this area [was] under-developed" and that there was "quite a bit of controversy and uncertainty" as to whether the "identify-all-claim-types" approach was correct. Plfs. Rule 56.1 Stmt. ¶¶ 86, 111. Whatever weight Fox's opinions are ultimately given in the reasonableness inquiry, that advice is not enough to secure summary judgment in Takeda's favor.

In sum, neither party has established beyond dispute that Takeda's misstatements in the January 2010 Letter were objectively reasonable or unreasonable, which precludes summary judgment at this time.[12] The underlying factual issues—industry practice and legal advice—will thus be sent to the jury, and the parties will have ample opportunity to propose the appropriate way to do so in advance of trial. *See, e.g.*, *303 W. 42nd St. Enters.*, 2000 WL 666339, at *4, 11–12 (Sand, J.) (discussing special verdict asking jury to assess industry practice). The Court will then factor the jury's determinations on these fact issues into its ultimate legal ruling on objective reasonableness. *Cf. Zellner*, 494 F.3d at 368 ("Once the jury has resolved any disputed facts that are material to the . . . immunity issue, the ultimate determination of whether the [defendant]'s conduct was objectively reasonable is to be made by the court.").

b. Subjective Good Faith

There also remains a fact dispute over whether Takeda believed in good faith that the "identify-all-claim-types" theory was correct. Takeda insists that it believed that it was required to describe the Patents as "drug product," primarily because it received legal advice to that effect from Fox and the Hogan team. *See* Takeda Opp. at 47. Plaintiffs, meanwhile, argue that a

[12] There may be instances in which plain language is so ambiguous, or regulatory policy so favorable, that a defendant's mistake will be objectively reasonable without regard for industry practice—or in other words, that any factual dispute over industry practice would be immaterial. Although the January 2010 Submission does meet that standard, the Court confronts a situation like this below with the May 2010 Letter.

reasonable jury would have to conclude that Takeda made those misstatements in bad faith, as its true purpose was to delay generic entry. *See* Plfs. Br. at 48. They cite to internal emails suggesting that Takeda hired Fox in order to find a way to force Teva to file a Paragraph IV certification, which could indicate bad faith. *See id.* Plaintiffs also point out that Takeda switched to an entirely different theory in its May 2010 Letter—the "induced-infringement" theory—which suggests that it might have simply been using outside counsel to devise outcome-oriented legal positions as opposed to dispassionate analysis.

Neither party is entitled to summary judgment on subjective good faith. As a baseline, "[q]uestions of intent" like subjective intent "are usually inappropriate for disposition on summary judgment." *Nat'l Union Fire Ins. Co. of Pittsburgh v. Turtur*, 892 F.2d 199, 205 (2d Cir. 1989). That is the case here. Although a reasonable jury could be persuaded that Takeda truly believed it was required to identify all claim types present in the Patents, it could just as easily side with Plaintiffs. Indeed, emails sent by Takeda's in-house team stated that it was looking for ways to "maximize the likelihood" that Teva would be forced to file a Paragraph IV certification, and revealed that Fox was put in charge of drafting the January 2010 Submission for that very purpose. Arnold Decl. Ex. 53. Those statements alone could support an inference that Takeda's motivation in filing the January 2010 Submission was to delay Teva, as opposed to a good-faith attempt to comply with its regulatory obligations. The advice Takeda received from its outside counsel, moreover, was far from adamant that the "identify-all-claim-types" theory was required. As Fox himself told Takeda, the "law" on patent descriptions was "under-developed, with most of it being agency-made in letters and petition responses, but with little in the way of judicial precedent to back up the FDA's claim-by-claim approach to certification described in the Prandin [decision]." *Id.* Ex. 49 at 4. Several months later, he further commented that "there remains quite a bit of

controversy and uncertainty as to whether the '584 and '404 patents would be considered 'method of use patents' and only method of use patents, for purposes of allowing generic[s] to use section viii statements, rather than patent certifications, to address these patents." Pls. Rule 56.1 Stmt. ¶ 111. A reasonable jury could infer from statements like these that Fox's advice was proposing opportunistic litigation positions—by exploiting "under-developed" areas of law—as opposed to setting out clear-cut rules that Takeda was required to follow.

In short, the parties have put forth "conflicting versions of events," and a reasonable jury could choose to side with either on this record. *Rule v. Brine, Inc.*, 85 F.3d 1002, 1012 (2d Cir. 1996). The parties' cross-motions for summary judgment are thus denied as to this element, which a jury will need to resolve at trial.

2. May 2010 Letter

The Court now turns to Takeda's May 2010 letter, which went even further than the January 2010 Submission and asserted that the Patents claimed ACTOS. As noted, if Takeda is found liable based on the January 2010 Submission (and not entitled to the regulatory compliance defense for it), then the May 2010 Letter may be redundant, as liability would already be established based on the earlier statement. But if the regulatory compliance defense shields Takeda from liability for the January 2010 Submission, then Takeda could still be found liable based on the May 2010 Letter, since the statements therein were also anticompetitive. The Court must thus decide whether Takeda or Plaintiffs are entitled to summary judgment as to either prong of the regulatory compliance defense as to the May 2010 letter. As explained below, it concludes that Takeda's statements that the Patents "claimed" ACTOS were objectively reasonable as a matter of law, but that there remains a dispute over its subjective good-faith belief that only a jury may resolve.

a. Objective Reasonableness

Starting with the reasonableness prong, Takeda argues that its assertion in the May 2010 Letter that the Patents "claim[ed] the ACTOS drug product" was objectively reasonable. Reed Decl. Ex. 79 at 12. According to Takeda, it believed that the Listing Requirement set forth an "induced-infringement" approach, under which a patent "claimed" a drug if it included at least one claim that recites at least a component of the drug (including in a combination claim) *and* that could reasonably be asserted in an infringement suit against an unauthorized seller of the drug. *See ACTOS II*, 417 F. Supp. 3d at 362–63 (summarizing this theory in connection with Takeda's motion to dismiss). This belief, it says, flowed from the text of the Listing Statute and Regulation, both of which include an "Infringement Clause" that references possible claims of infringement made against such unauthorized sellers. *Takeda II*, 11 F.4th at 134.[13] In Takeda's view, that Infringement Clause modified the preceding language about "claims the drug," which would mean that a patent "claims" the drug so long as it (1) recites at least a component of the drug, and (2) could reasonably be asserted against an unauthorized seller of the drug product. The Patents would meet that definition, as they recited combinations of ACTOS and other drugs and could be asserted in an induced infringement claim against an unauthorized seller of ACTOS because the labeling recommends its prescription in combination with those other drugs. *See ACTOS II*, 417 F. Supp. 3d at 362–63 (explaining Takeda's theory).

[13] *See also* 21 U.S.C. § 355(b)(1) ("The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."); 21 C.F.R. § 314.53(b)(1) ("An applicant . . . shall submit information on each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.").

Although this Court and the Second Circuit have already rejected the "induced-infringement theory," *see id.*, it was an objectively reasonable interpretation of the Listing Requirement in 2010. Unlike Takeda's "identify-all-claim-types" theory, there is textual support for the "induced-infringement" theory in both the Listing Statute and Regulation, in the form of the Infringement Clause. And on account of that textual support, the Listing Requirement could plausibly be read as requiring the "induced-infringement" theory. In fact, this Court expressly found that there was "a substantial ground for difference of opinion" as to whether Takeda's theory was correct, which prompted the Court to take the unusual step of certifying the issue for immediate interlocutory review. *ACTOS IV*, 2020 WL 433710, at *2 (noting also the "strong arguments" Takeda raised in support of its theory). This textual uncertainty makes this case similar to *Organon*, where another court found that the Listing Requirement was so ambiguous that a defendant's possible misinterpretation of it was objectively reasonable. *See* 293 F. Supp. 2d at 460 (finding section of Listing Regulation "capable of two equally plausible interpretations"). The Court is thus persuaded that, based on the text alone, Takeda's "induced-infringement" theory was an objectively reasonable interpretation of the Listing Requirement. Because there thus is no need to look to other factual evidence, the Court finds that Takeda has satisfied the reasonableness prong as a matter of law as to the May 2010 Letter.

b. Subjective Good Faith

Even so, Takeda must still show that it made the May 2010 Letter in subjective good faith. This requires Takeda to show that it subjectively believed the "induced-infringement" theory was the correct interpretation of the Listing Requirement, as opposed to a strategy that would allow it to force generics to file Paragraph IV certifications. In arguing that it acted in good faith, Takeda again cites the fact that it received outside legal advice that the "induced-infringement" theory was

correct, namely the memo it received from Munger Tolles. *See* Takeda Br. at 22; Takeda Opp. at 48.

Once again, however, there is a genuine dispute as to whether Takeda subjectively believed the "induced-infringement" theory was correct. First and foremost, there was disagreement within Takeda over whether the Patents in truth "claimed" ACTOS, which could lead a reasonable jury to rule against it on this issue. One attorney at Hogan, for instance, stated outright that "the claims [of the Patents] indisputably do not apply to the product [ACTOS]." Arnold Decl. Ex. 63 at 16. Even Fox expressed skepticism that Takeda could truthfully make such an assertion. After Takeda's in-house counsel suggested that an FDA document indicated that the Patents claimed ACTOS, Fox told him he was wrong. *See* Arnold Decl. Ex. 67 at 2. Another in-house attorney even proposed deleting the language in the May 2010 Letter stating that the Patents "claimed" ACTOS, which could indicate to a jury that Takeda was unsure if those statements were correct. *See* Plfs. Rule 56.1 Stmt. ¶ 112; Arnold Decl. Ex. 70 at 13.

Takeda also makes much of the memo it received from Munger Tolles, but that is not conclusive either. It is true that the memo provided a possible justification for asserting that the Patents "claimed" ACTOS. *See* Reed Decl. Ex. 75 at 2. But it also acknowledged that it was providing only a "colorable argument" for making those assertions, not that those statements were outright correct under the Listing Requirement. *Id*. at 4, 8. And when Takeda asked Munger Tolles for the memo, it did not ask for the firm's independent opinion as to the meaning of the Listing Requirement, but instead asked it to explore whether there was any "good[-]faith basis" for "representing" that the Patents claimed ACTOS. *Id.* at 2. A reasonable jury could infer from those circumstances that Takeda was merely in search of a way to delay the generics as opposed to a good-faith attempt to comply with its regulatory obligations.

Because Takeda's motivations in submitting the May 2010 Letter are far from clear, there is a genuine dispute as to whether it made that submission in subjective good faith. The parties' cross-motions for summary judgment are thus denied on this issue as well.[14]

II. *Daubert* Motions

Both parties also filed *Daubert* motions to exclude various expert opinions. Several of these motions sought to exclude expert opinions on damages, *see* Dkt. 629, 633, 641, 644, which are not at issue in either party's summary judgment motion, *see* Dkt. 814 (joint letter agreeing to defer argument on these issues). Those motions are thus denied as premature without prejudice to re-filing them in advance of trial. That leaves three *Daubert* motions remaining, to which the Court now turns.

As discussed below, the Court agrees with Plaintiffs that Takeda's regulatory experts may not testify about what the Listing Requirement legally required, that Takeda's conduct was "reasonable" or that the legal advice Takeda received was sound. They will, however, be permitted to give background testimony as appropriate on the Listing Requirement and to testify about industry practice. As for Takeda, the Court agrees that Plaintiffs' patent expert may not testify about how a reasonable patent attorney would have interpreted FDA regulations, though he may give background and industry practice testimony where proper. The Court also rejects Takeda's motion to preclude Plaintiffs' market expert as unreliable.

[14] Takeda also argues that its May 2010 Letter is protected by the *Noerr-Pennington* doctrine, Takeda Opp. at 32, but the Court disagrees. Among other things, this doctrine can immunize antitrust defendants from conduct that constitutes "petitioning activity" aimed at "persuading the government of a position or expressing views and wishes concerning government decisions." *La. Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-cv-7343 (HB), 2008 WL 169362, at *1, 3 (S.D.N.Y. Jan. 18, 2008) (citing *E. R.R. Presidents Conf. v. Noerr Motor Freight Inc.*, 365 U.S. 127 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965)). This immunity, however, does not apply when a defendant petitions the government to act "in a merely ministerial or non-discretionary capacity in direct reliance on the representations made by private parties"—which describes the Section 314.53(f) listing challenge to a tee. *In Re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 369 (S.D.N.Y. 2002). Takeda thus finds no refuge in this doctrine.

A. Plaintiffs' Motion to Exclude the Hoxie, Lassman and Lietzan Opinions

Plaintiffs move to exclude the expert opinions and testimony of three lawyers: Thomas Hoxie, Scott Lassman and Erika Lietzan. *See* Dkt. 623 ("Plfs. Regulatory Daubert Br."). In brief, Hoxie is a patent attorney who was formerly the head of patents for Novartis Group. *See* Hoxie Report ¶¶ 3–4. He offers opinions on a range of topics, including whether Takeda was required to list the Patents in the Orange Book, whether its descriptions of those patents were proper and reasonable and whether the Munger Tolles memo was sound. *See id.* ¶ 10. Lassman is an FDA regulatory expert who offers opinions on the Hatch-Waxman regulatory framework and whether Takeda's descriptions of the Patents in its NDA were correct and reasonable. *See* Lassman Report ¶¶ 17–21. Lietzan is a law professor and pharmaceutical regulatory expert who offers opinions on whether Takeda's patent descriptions were reasonable as well as whether it was reasonable to seek outside counsel to help prepare its responses to the Sandoz Citizen Petition. *See* Arnold Decl. Ex. 84 ("Lietzan Report") ¶ 7.

Plaintiffs' motion seeks to exclude their expert opinions on four topics.[15] First, Plaintiffs move to exclude testimony from these experts as to their opinions of what the law required. *See* Plfs. Regulatory Daubert Br. at 12. This request is granted. "As a general rule an expert's testimony on issues of law is inadmissible." *Bilzerian*, 926 F.2d at 1294. Instructing the jury on the content and scope of the law is the "exclusive" duty of the court. *In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. 2d 61, 69–70 (S.D.N.Y. 2001). Permitting a witness to testify about their own "understanding of the meaning and applicability" of statutes and regulations would run roughshod over that venerable rule. *F.A.A. v. Landy*, 705 F.2d 624, 632 (2d Cir. 1983).

[15] Hoxie, Lassman and Lietzan also offered various opinions on causation as it relates to damages, which was not at issue in either party's summary judgment motion. *See* Dkt. 814 (joint letter agreeing to defer argument on these issues). The motions to exclude their causation opinions are thus denied as premature with leave to re-file in advance of trial.

Takeda proposes to do just that. Its experts seek to testify, among other things, that Takeda's descriptions of the Patents were correct based on their own interpretations of the Listing Statute and Regulation. *See, e.g.*, Hoxie Report ¶¶ 10(b), 100–04 ("Takeda did not mischaracterize the '584 and '404 patents to the FDA."); Lassman Report ¶¶ 17, 56, 61 ("Takeda's identification of the '584 and '404 patents as 'drug product' patents . . . fully complied with the Hatch-Waxman Act, [the] FDA's pre-2003 regulations, and [the] FDA's then-existing policies."). But "there is no such thing as an expert opinion when it comes to interpreting a statute unless that opinion belongs to a court"—and "it remains [the] Court's exclusive duty and province to 'say what the law is.'" *In re Initial Pub. Offering Sec. Litig.*, 174 F. Supp. at 69–70 (quoting *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803)). Worse, these legal opinions are incorrect. As the Court already determined—in 2019 and again today—Takeda's patent descriptions were wrong, and its experts may not offer opinions to the contrary.

To be sure, it may be appropriate for one or both parties to offer expert testimony on the "general background" of Hatch-Waxman regulation. *See Bilzerian*, 926 F.2d at 1294–95 (permitting expert testimony on "general background o[f] federal securities regulation"). Such testimony on "the complicated regulatory framework of the FDA" will be "helpful"—if not essential—"to a jury in this case." *In re Mirena IUD Prods. Liab. Litig*, 169 F. Supp. 3d 396, 467–68 (S.D.N.Y. 2016). At the same time, however, no expert will be permitted to offer their opinions on issues of regulatory law that are (or were) in dispute, such as whether Takeda's "identify-all-claim-types" or "induced-infringement" theories were correct. *See Coan v. Dunne*, No. 15-cv-00050 (JAM), 2019 WL 2169879, at *1 (D. Conn. May 17, 2019) (permitting expert testimony on "background or subsidiary principles of law . . . that are not directly at issue"). As even Takeda recognizes, there may be limitations on how much background testimony will be appropriate,

which will come into focus as trial approaches. *See* Dkt. 668 at 15 (Takeda arguing for more background testimony because "it is unlikely that the jury will be instructed in detail on the complex statutory and regulatory structure governing patent listings."). The parties may therefore re-raise this issue of background testimony in advance of trial.[16]

Second, Plaintiffs move to exclude the experts' opinions that Takeda's misdescription of the Patents was based on a "reasonable" interpretation of FDA law. *See* Plfs. Regulatory Daubert Br. at 22. According to Plaintiffs, whether Takeda's misinterpretation was objectively reasonable is a question of law that is purely within the Court's purview, and is also the type of "ultimate issue" to which experts may not testify. The Court agrees on both fronts. As already explained, objective reasonableness is ultimately a question of law that the Court must decide. *Cf. Albrecht*, 587 U.S. at 316 ("[J]udges are better suited than are juries to understand and to interpret agency decisions in light of the governing statutory and regulatory context."). And whether Takeda's misinterpretation was reasonable is also an "ultimate issue," which cannot be the subject of expert testimony, as Takeda's own cases recognize. *See In re Mirena*, 169 F. Supp. 3d at 474 (citing *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 n.16 (S.D.N.Y. 2009)) (permitting expert testimony on regulatory scheme because ultimate issue was "state law claims of strict liability and negligence, not FDA regulatory violations"). Takeda's experts thus may not offer testimony on the issue of reasonableness itself.

Third, Plaintiffs move to exclude the experts' opinions on industry practice, and whether others in the industry shared Takeda's mistaken view that the Listing Requirement required the "identify-all-claim-types" approach. *See* Plfs. Regulatory Daubert Br. at 17. Plaintiffs argue that

[16] Plaintiffs also seek to exclude "irrelevant" opinions about whether the Patents needed to be identified at all, and what the impact of the 2003 changes to the Listing Regulation was. *See* Plfs. Regulatory Daubert Br. at 21. The Court agrees that such opinions do not appear particularly relevant, but may potentially be a proper topic of background testimony down the line.

these opinions are "inadmissible opinions of law" and "flatly contradict[ed]" by the Second Circuit's holding in *Takeda II*, which rejected Takeda's argument that the "induced-infringement" theory was consistent with industry practice. *Id.* at 16, 19 (citing *Takeda II*, 11 F.4th at 136).

That is not quite correct. Unlike testimony on the legal issue of reasonableness itself, testimony about industry practice is a proper topic of expert testimony. As the Court explained above, and as Plaintiffs themselves have argued, "industry practice" is an underlying factual issue that is well suited for jury determination. *Bilzerian*, 926 F.2d at 1295; *see* Dkt. 822 at 3–4 (Plaintiffs arguing that industry practice is subsidiary fact that jury could decide when in dispute). Testimony about industry practice is thus not an opinion of law, and is indeed appropriate to present to a jury tasked with making a determination on industry practice. Nor is the Court persuaded that introducing these opinions on industry practice would contradict *Takeda II*. There the Second Circuit merely held that the behavior of generics in their ACTOS ANDAs was "at best weak corroboration of industry understanding." 11 F.4th at 136. That leaves open the door for Takeda to offer more evidence of industry practice, like the expert opinions here, that could tip the scale in its favor.

Takeda's experts will thus be able to present their opinions about industry practice to the jury. Of course, if Takeda's experts cross over the line and offer opinions on the ultimate issue of *reasonableness*, that testimony will be excluded. *See Bilzerian*, 926 F.2d at 1295 ("[T]estimony encompassing an ultimate legal conclusion based upon the facts of the case is not admiss[i]ble, and may not be made so simply because it is presented in terms of industry practice."). Takeda's experts will also be held to the usual limits on testimony and may not offer new opinions beyond those disclosed in their reports. *See, e.g.*, Dkt. 822 (objecting to proposed expert opinion as not properly disclosed under Fed. R. Civ. P. 26(a)(2)(B)(i)).

Fourth, Plaintiffs seek to exclude Hoxie's and Lietzan's opinions about the legal advice Takeda received from Hogan and Munger Tolles. *See* Plfs. Regulatory Daubert Br. at 37, 40. The Court agrees that such testimony should be excluded. In the opinion at issue, Hoxie describes the Munger Tolles memo and concludes that it is "well-grounded." Hoxie Report ¶¶ 105–12. But this conclusion is merely Hoxie "parrot[ing] the findings" of Munger Tolles, which is not a permissible basis for an expert opinion. *Bank of N.Y. Mellon Tr. Co., Nat'l Ass'n v. Solstice ABS CBO II, Ltd.*, 910 F. Supp. 2d 629, 640 (S.D.N.Y. 2012) ("An expert cannot simply parrot the findings of another arrived at in another context." (internal quotation marks omitted)). Hoxie's opinion that the memo was "well-grounded," moreover, is effectively an opinion of law—namely that the position taken in the memo was reasonable—which is not permitted for the reasons already stated. While Takeda may introduce evidence of the Hogan and Munger Tolles legal advice as it relates to regulatory compliance, it may not bolster or parrot that advice through its experts.

As for Lietzan, she offers the opinion that it was reasonable for Takeda to rely on the opinions of Fox and Hogan. *See* Lietzan Report ¶ 14. That testimony is not permissible either. Whether Takeda's interpretation of the Listing Requirement was reasonable is a legal question reserved for the Court alone. She may not give opinions directly on that subject, and any testimony related to reasonableness must generally be limited to the factual issues that will be put to the jury, such as industry practice.

B. Takeda's Motion to Exclude the Donatiello Opinion

Next is Takeda's motion to exclude the opinion of Guy Donatiello. Donatiello is a former in-house patent attorney who offered an opinion on how a "reasonable patent attorney" would have interpreted FDA regulations. Reed Decl. Ex. 5 ("Donatiello Report") ¶¶ 4–5. Takeda moves to preclude his opinion because (1) how a reasonable patent attorney would interpret those

regulations is not relevant, as the applicable regulations are not patent-specific but a matter of FDA regulatory law, and (2) it would, relatedly, risk confusing the jury because the reasonableness prong of the regulatory compliance defense is not anchored to how a reasonable patent attorney would interpret the regulations.

The Court agrees that these opinions are impermissible. As covered at length above, whether Takeda's understanding of regulatory law was reasonable is a question of law for the Court. Donatiello thus may not provide his own opinions on that ultimate issue. And as Takeda rightly notes, such opinions would be irrelevant and confusing, as the reasonableness prong does not ask whether a defendant's conduct was reasonable in the eyes of a patent attorney—it asks whether it was reasonable from the perspective of an actor in that specific regulatory industry. *Cf. In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 544 (S.D.N.Y. 2004) (excluding expert testimony about ethics in products liability case because "ethical character of [defendants'] actions simply [were] not relevant to the[] lawsuits"). As with Takeda's experts, Donatiello may still provide opinions on other appropriate topics, such as background information about the regulatory scheme and industry practice, subject to the usual limits on admissibility.

C. Takeda's Motion to Exclude the Starr Opinion

Lastly, Takeda moves to exclude parts of the opinion of Dr. Martha A. Starr. Dr. Starr is an economist who seeks to offer opinions that Takeda possessed monopoly power and that the relevant market is limited to ACTOS and its generics (and does not include other drugs that could be prescribed in place of ACTOS). *See* Arnold Decl. Ex. 92 ("Starr Report") ¶¶ 5–11. She also offered rebuttal opinions in response to Dr. Jena's contrary opinions that the relevant market includes those other diabetes drugs. *See id.* Ex. 93 ("Starr Rebuttal Report") ¶ 2. Takeda's motion seeks to exclude one of Dr. Starr's affirmative studies as well as parts of her rebuttal to Dr. Jena's

opposing studies, arguing that both opinions should be excluded as unreliable. The motion is denied.

The study that Takeda seeks to exclude is a twelve-month "natural experiment" that she performed on the market for anti-diabetes drugs following entry of generic ACTOS. *See* Starr Report ¶ 93. In this study, Dr. Starr sought to determine whether (and to what extent) patients and prescribers switched from antidiabetics similar to ACTOS to generic pioglitazone once it became available in August 2012. If such switches occurred, it would indicate that those other antidiabetics were substitutes for pioglitazone, which in turn would mean that the relevant market for ACTOS included not only its generic equivalents but also those other antidiabetics. *See id.* ¶ 96. According to her study, however, there was no significant evidence of swaps from other antidiabetics to generic ACTOS, which supported her opinion that the relevant market did not include other antidiabetics. *See id.* ¶ 97–98.

Takeda says this study was unreliable because its length—one year—was "arbitrary." Dkt. 627 at 9. According to Takeda, Dr. Jena replicated the study on an eighteen-month timeline instead of twelve and found significant evidence of the *opposite* outcome: that many patients and prescribers switched from other drugs to generic ACTOS once it became available. Dr. Starr also admitted at her deposition, moreover, that she has run similar studies over longer time periods.

These arguments, however, go to weight and not admissibility. First off, while Dr. Starr has sometimes used longer windows for past studies, she has also used shorter ones—which confirms that twelve months was not unusually or arbitrarily short. *See* Dkt. 628 Ex. C ("Starr Dep.") at 122–23. More critically, Dr. Starr also provided a sound reason for picking twelve months: A cluster of new drugs were released at around that point, which would have been difficult to control for in the study. *See id.* at 129–30. As she explained in greater detail in her rebuttal

report, it is important to adjust studies to account for such "confounding events," and one way of doing so is by selecting an "estimation window[]" that avoids them. Starr Rebuttal Report ¶¶ 37–38. That separates this case from others in which experts "cherry-picked" data, or where "very minor changes in arbitrarily selected model parameters c[ould] entirely alter the model's conclusions." *See Reed Constr. Data Inc. v. McGraw-Hill Cos., Inc.*, 49 F. Supp. 3d 385, 400 (S.D.N.Y. 2014), *aff'd*, 638 F. App'x 43 (2d Cir. 2016). This is not a case in which doing an eleven- or thirteen-month study would have yielded drastically different results. Indeed, Dr. Jena achieved a different outcome only by extending Dr. Starr's study by half its original runtime—far from a "very minor change[]." *Id.*

Nor is the Court persuaded by Takeda's attempt to exclude Dr. Starr's critique of Dr. Jena's counterstudy. In her critique, Dr. Starr re-ran Dr. Jena's eighteen-month counterstudy by adding two further controls to account for the "prescribing of newly available drugs and new clinical findings related to the cardiovascular risk of [certain antidiabetics]." Starr Rebuttal Report ¶ 39. Once those controls were added, the favorable results Dr. Jena originally found disappeared. *Id.* According to Dr. Starr, this illustrates the risks of running longer studies, as Dr. Jena did, due to the greater chance that confounding events will occur and throw off results.

Takeda offers two reasons why this analysis is unreliable, neither of which is persuasive. First, it asserts that Dr. Starr did not control for newly available drugs in her own study, which must either mean that (1) her own study is unreliable for lack of controls, or (2) her criticism of Dr. Jena for omitting such controls is unsound. But as Plaintiffs explain, there was little need for Dr. Starr to include such controls in her twelve-month study, precisely because it was cut short of the time where these drugs were prescribed at significant levels. *See* Starr Dep. 133–36. Her criticism of Dr. Jena is that he extended her study to periods in which those prescriptions ticked

up, which opened the door for confounding results—a valid point. To the extent Takeda believes that Dr. Starr should have controlled for other drugs in her own study, or improperly selected those she did control for, it should make those arguments to the jury. *See S.E.C. v. Vali Mgmt. Partners*, No. 21-453, 2022 WL 2155094, at *2 (2d Cir. June 15, 2022) ("Contentions that an expert's assumptions are unfounded or gaps or inconsistencies in the reasoning leading to the expert's opinion go to the weight of the evidence, not its admissibility." (internal quotation marks omitted)).

Second, Takeda argues that Dr. Starr's analysis of the second control—to account for new clinical findings that some drugs posed heart risks—is unreliable because she did not "read" those studies and did not have the "clinical expertise to interpret their results." Dkt. 627 at 10. That argument too is rejected. An economist need not be a trained physician in order to opine that demand for a drug might go down if studies link it to serious health problems. And at any rate, Dr. Starr explained that Takeda's own business documents recognized that the studies could "weigh[] down demand" for these drugs, which makes it appropriate for her to explore whether econometric models should control for such trends. Starr Dep. 147–48.

CONCLUSION

For these reasons, Takeda's motion for summary judgment is DENIED, and Plaintiffs' motion for partial summary judgment is GRANTED with respect to willful maintenance but DENIED as to monopoly power and the regulatory compliance defense. Plaintiffs' motion to exclude the testimony of Thomas Hoxie, Scott Lassman and Erika Lietzan is GRANTED IN PART and DENIED IN PART, Takeda's motion to exclude the testimony of Guy Donatiello is GRANTED and Takeda's motion to exclude the testimony of Dr. Martha Starr is DENIED. The remaining *Daubert* motions are DENIED as premature with leave to re-file in advance of trial.

The Clerk of Court is respectfully directed to terminate the motions pending at docket numbers 622, 624, 629, 633, 637, 641, 644, 706, 709 and 772.

SO ORDERED.

Dated: March 31, 2025
New York, New York

Ronnie Abrams
United States District Judge